# Plaintiffs' Memorandum in Opposition to Joint Motion for Summary Judgment for Failure to Prove Fault Element of Public Nuisance Claims

# Ex 13 – 5-17-19 Prevoznik Dep Ex. P46 Excerpts


# Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia

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## II. Executive Summary

The opioid epidemic is the worst drug crisis in America's history. According to the Centers for Disease Control and Prevention, more than 351,000 lives have been lost to opioid overdoses since 1999, with no signs of abating. Far more people die from the misuse of opioids in the United States each year than from road traffic accidents or violence. Public health officials are alarmed that the opioid problem has helped drive a decline in U.S. life expectancy at a time when life expectancy is improving in many places around the world.

As part of its legislative responsibilities to help protect public health, the House Energy and Commerce Committee in the 115th Congress intensified efforts to understand how the nation got to a crisis point with the opioid epidemic, and to find solutions to address this problem. In early 2017, the Committee became interested in allegations of "opioid-dumping," a term to describe inordinate volumes of opioids shipped by wholesale drug distributors to pharmacies located in rural communities, such as those in West Virginia. These allegations were highlighted in reports by the *Charleston Gazette-Mail* in West Virginia and the *Washington Post*.

In May 2017, the Committee opened a bipartisan investigation into the allegations. From press reports and this investigation, the Committee learned of opioid shipments in West Virginia that shocked the conscience:

- Over 10 years, 20.8 million opioids were shipped to pharmacies in the town of Williamson, home to approximately 3,000 people.
- Another nearly 9 million opioids were distributed in just two years to a single pharmacy in Kermit, West Virginia, population 406.
- Between 2007 and 2012, drug distributors shipped more than 780 million hydrocodone and oxycodone pills to West Virginia.

These troubling examples raised serious questions about compliance with the Controlled Substances Act (CSA), administered by the Drug Enforcement Administration (DEA).

In undertaking this investigation, the Committee sought an in-depth, unprecedented look into what happened that led to inordinate shipments of opioids to small, rural pharmacies in southwestern West Virginia, part of the epicenter of the nation's opioid epidemic and the state with the highest drug overdose death rate in the country. This examination was intended to review evidence, mostly documents, from the three largest wholesale drug distributors in the U.S. as well as those from two other regional distributors that were significant suppliers to West Virginia pharmacies. The companies whose distribution was reviewed are AmerisourceBergen Drug Corp., Cardinal Health, Inc., H.D. Smith Wholesale Drug Co., McKesson Corp., and Miami-Luken, Inc. The investigation also included review of some internal documents from the DEA. From this review, the Committee sought to determine the effectiveness of DEA enforcement and to evaluate the extent that distributors implemented controls to prevent diversion of opioids. This investigation is a start to establish some accountability and

understanding about the epidemic, but this inquiry is only a look at a piece of the overall puzzle. There are other actors involved in the epidemic including manufacturers, pharmacies, physicians, and drug traffickers.

This report presents case studies of opioid distribution to southwestern West Virginia pharmacies over the last decade. The findings from these individual case studies are not necessarily generalizable of the conduct of the distributors more broadly. However, the case studies—taken altogether with the sheer number of opioids sent to these small towns—raise sufficient concerns as to whether these companies fulfilled their legal obligations to prevent drug diversion.

The DEA is the federal agency tasked with administering and enforcing the CSA and regulating more than 1.73 million registrants licensed to manufacture, distribute, and prescribe controlled substances in the United States. This law established schedules of controlled substances and provided the authority for the DEA to register entities engaged in the manufacture, distribution, or dispensation of controlled substances. The CSA was designed to combat diversion by providing for a closed system of drug distribution, in which all legitimate handlers of controlled substances must obtain a DEA registration, and as a condition of maintaining such registration, must take reasonable steps to ensure their registration is not being used as a source of diversion.

The DEA regulations specifically require all distributors to report suspicious orders of controlled substances, in addition to the statutory responsibility to exercise due diligence to avoid filling suspicious orders. In addition, federal regulations impose additional security control requirements on nonpractitioner DEA registrants, such as distributors including, but not limited to:

- "Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State-controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance."[1]

- "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division of the Administration in his region of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[2]

As the opioid epidemic began to surge, the DEA by 2005 realized that traditional policing of individual doctors and pharmacies was no longer an effective approach against the oncoming avalanche of opioids from rogue internet pharmacies and pill mills. Instead, DEA's focus turned to the drug wholesale distributors, a chokepoint in the pharmaceutical supply chain, who transfer drugs from manufacturers to businesses such as clinics, hospitals, and pharmacies where they

[1] 21 C.F.R. § 1301.74(a).
[2] 21 C.F.R. § 1301.74(b).

can be dispensed to patients. Distributors in previous years had not received enforcement attention from the DEA. The new focus looked for greater impact with a highly consolidated industry given that the three major drug distributors—AmerisourceBergen, Cardinal Health, and McKesson—control about 85 percent of the drug supply.

Beginning in 2005, the DEA undertook a series of initiatives meant to educate wholesale drug distributors about their legal obligations to prevent controlled substance diversion. The DEA's "Distributor Initiative" included one-on-one meetings with wholesale distributors in which DEA officials provided specific examples regarding distributors' own customers whose ordering habits were suggestive of trends indicating the presence of diversion and illicit internet pharmacies. Of the five distributors investigated by the Committee, AmerisourceBergen, Cardinal, H.D. Smith and McKesson each had one-on-one meetings with DEA as part of this initiative. In addition, during 2006 and 2007, the DEA sent a series of three letters sent to all DEA-registered distributors, outlining their legal obligations to conduct due diligence and report suspicious orders.

Apparently, the DEA soon realized that the largest distributors were not taking their compliance requirements with sufficient seriousness. In 2007 and 2008, the DEA took enforcement action through legal settlements against the three largest wholesale distributors in the U.S. for alleged violations of the CSA, with multi-million-dollar fines involving two of them.

Despite these settlement agreements, and the subsequent policy enhancements that the three distributors made in their aftermath, the Committee found the distributors continued to ship large volumes of opioids into West Virginia. The three largest wholesale drug distributors in the United States, AmerisourceBergen, Cardinal Health, and McKesson, sent more than 900 million doses of hydrocodone and oxycodone to West Virginia between 2005 and 2016. Cardinal Health was the largest supplier of controlled substances to West Virginia out of the five companies examined as part of the Committee's investigation and distributed more than 366 million doses of hydrocodone and oxycodone to West Virginia pharmacies between 2005 and 2016. From April 2006 through 2016, McKesson supplied 299.87 million doses of hydrocodone and oxycodone to West Virginia pharmacies. AmerisourceBergen distributed 248.16 million doses of hydrocodone and oxycodone to West Virginia pharmacies between 2005 and 2016. Likewise, regional distributors, H.D. Smith and Miami-Luken also made inordinate shipments during this timeframe.

According to DEA analysis of market data, the hydrocodone disbursements to some pharmacies were as many as six times higher than the annual amount an average rural West Virginia pharmacy received. At the same time large amounts of opioids were being supplied to West Virginia, the DEA had data demonstrating the increasing problem with controlled substance diversion in the state.

As explained in greater detail in this report, the extraordinary volume of shipments in West Virginia was a signal of possible breakdowns in distributors' oversight of their customers, including their suspicious order monitoring systems. Yet the actions taken by both distributors and the DEA contributed to—and failed to stop—this problem.

Among the Committee's findings, distributors suffered a series of breakdowns or had a lack of follow through in their due diligence evaluations of prospective pharmacy customers. As demonstrated in the report, the Committee found instances of insufficient due diligence by distributors who merely required pharmacies to complete new customer applications. There were cases where data submitted by a new customer was not critically analyzed to identify any red flags of controlled substance diversion. For example, potential red flags regarding a pharmacy's prescribing physicians that raised concerns about possible diversion were not questioned.

After distributors brought pharmacies on board as customers, the investigation found instances where there were failures to monitor the volume of controlled substances sold to customers. Some distributors used thresholds to track customers' purchases of controlled substances and flag orders as suspicious when purchases exceed those limits. But some of the thresholds were assigned arbitrarily, and not effective. The Committee found instances in which distributors set thresholds but failed to enforce them, assigned artificially high hydrocodone threshold limits with little to no documented justification, or continued to raise threshold levels without thoroughly investigating or documenting the justifications presented by a customer pharmacy.

Despite efforts by DEA to educate distributors about their responsibility to report suspicious orders, the companies reviewed by the Committee failed to address suspicious order monitoring in critical ways. Rather than reporting individual suspicious orders as they were identified, some distributors reported a variety of other types information to DEA over the years. This information included excessive orders encompassing drug shipments that had already been shipped, and suspicious customers such as pharmacies with which distributors had terminated business relationships. Neither of these types of reports informed DEA about suspicious orders in real-time nor did they guarantee the suspicious orders reported to DEA were also blocked by the distributors. The Committee also found that one distributor lacked any formal order monitoring program. Rather, the distributor's employees relied on subjective criteria to identify orders it considered suspicious.

Another critical failure identified by the Committee involved instances in which distributors appeared to turn a blind eye to red flags of possible drug diversion. Despite available information, distributors, at times, took only minimal steps to investigate possible warning signs of diversion and continued to ship controlled substances to suspect pharmacies. In several cases, distributors either failed to fully investigate potentially troubling information they obtained from customer pharmacies or willfully ignored it. These failures raise substantial concern given that DEA has said existing knowledge of a geographic area's problem with controlled substance abuse is a factor that distributors should take into account when evaluating customers. West Virginia has the highest drug overdose rate in the country—meaning distributors should have been particularly attuned to any red flags encountered when conducting due diligence on pharmacies in the state.

Many suspect pharmacies highlighted throughout this report remain open. And while some of the distributors featured in this report have stopped doing business with these pharmacies, other distributors have stepped in to supply them. Even when one distributor

determines a pharmacy poses a risk of diversion, another may not investigate thoroughly enough to uncover the same red flags, or it may choose to ignore them. This revolving door of suppliers highlights the need for the DEA to provide oversight of DEA registrants—both distributors willing to turn a blind eye to signs of diversion and pharmacies engaged in pill mill operations.

Just as the Committee found failures in distributors' anti-diversion efforts, so too did it uncover gaps in the DEA's enforcement posture, both related to its capabilities nationwide and its oversight in West Virginia. One element that hindered DEA's ability to proactively identify diversion trends and target enforcement actions was the difficulty of utilizing data collected through its Automation of Reports and Consolidated Orders System (ARCOS). Pharmaceutical manufacturers and distributors are required to report their controlled substance transactions to the DEA under the CSA. The DEA relies on ARCOS to record and track the approximately 90 million controlled substance transactions reported every year. The system enables DEA to review the data so it can detect abnormal distribution patterns involving individual pharmacies and distributors or larger controlled substances sales trends across the U.S. At the time the opioid epidemic was worsening, however, DEA did not proactively use ARCOS data to investigate diversion trends. Rather, the data were used reactively to strengthen cases once DEA identified targets through other means.

In 2015, DEA created a new online reporting system meant to simplify the ARCOS reporting process and immediately flag errors in registrants' reports. Improvements have enabled DEA to proactively analyze ARCOS and, in 2017, DEA headquarters began sending target packages to field divisions that included analysis of ARCOS data, including drug sales trends within the division, and top pharmacy purchasers. Despite these improvements, DEA still lacks a centralized suspicious order reporting system. Unless dictated by a memorandum of agreement, distributors report suspicious orders to local DEA offices that hold varying regulatory interpretations, resulting in inconsistent handing of the reports. The Committee found evidence that this may have led to confusion on the part of distributors regarding reporting requirements.

The Committee also uncovered several factors that constrained DEA's administrative enforcement actions during the timeframe reviewed. DEA's use of Immediate Suspension Orders (ISOs) dropped precipitously in recent years, from 58 ISOs in Fiscal Year (FY) 2011 to 46 in FY 2012, reaching a low of five in FY 2015. ISOs are an enforcement action the agency relies on to immediately revoke the registrations of entities like doctors, pharmacies, and distributors suspected of drug diversion that pose an imminent danger. The DEA conceded that it had deferred ISOs against registrants—potentially jeopardizing the ability to protect public safety—to allow prosecutors to develop criminal cases. The delays happen often enough that DEA has indicated that it is exploring with DOJ a way to eliminate the indefinite delay. Thus far, DEA has not set any limit on the length of time it is willing to delay an ISO.

Another factor that appears to have limited DEA's use of ISOs was the evolution of the agency's enforcement strategy. In reaction to its interpretation of certain administrative or court rulings, DEA lawyers developed a more cautious approach and began to require additional levels of evidence on the front end of investigations before they would approve administrative action. This manifested, for example, in requests for medical expert testimony to support ISOs and other administrative action.

DEA officials have indicated that more could have been done in West Virginia to investigate and prevent controlled substance diversion, particularly in the 2006-2009 timeframe. However, DEA has not indicated in detail to the Committee what lessons were learned and how DEA could have acted sooner. In 2006, DEA had only two diversion investigators assigned to West Virginia and did not begin to devote significant resources to the state until 2015. Since then, the agency has increased personnel in the state, including through the assignment of an Assistant Special Agent in Charge who is based in Charleston, West Virginia rather than Washington, D.C. as was the case prior to 2016. Tactical diversion squads have also been deployed to West Virginia and in January 2018, DEA opened a new field division that oversees DEA's efforts in the Appalachian region, including Kentucky, Tennessee, and West Virginia.

Taken altogether, the Committee's report outlines a series of missteps and missed opportunities that contributed to the worsening of the opioid epidemic in West Virginia. This investigation identified flaws limiting the effectiveness of the distributors' compliance programs and DEA's enforcement. While focused on a narrow part of West Virginia, the report raises grave concerns about practices by the distributors and the DEA nationwide. The recently enacted SUPPORT for Patients and Communities Act, (H.R. 6), included several provisions to respond to these concerns. In addition, this report concludes with recommendations to help improve such programs and enforcement, including administrative changes and suggested legislative approaches.

- Distributors can obtain dispensing data from pharmacies that show the total volume of controlled substances dispensed by a pharmacy, including the method of payment and physician associated with each prescription.

- McKesson supplied Sav-Rite No. 1 with more than 5.66 million doses of hydrocodone and oxycodone in 2006 and 2007. Based on these two years alone, Sav-Rite No. 1 was McKesson's third largest hydrocodone and oxycodone purchaser in West Virginia between 2006 and 2017.

- McKesson's due diligence file for Sav-Rite No. 1 contained only one document, a November 2007 written declaration from the pharmacy's owner representing that the pharmacy sells only legitimate prescriptions.

- Family Discount Pharmacy in Mount Gay-Shamrock was McKesson's biggest purchaser of hydrocodone and oxycodone in West Virginia between 2006 and 2017. McKesson supplied the pharmacy with more than 5.91 million doses of hydrocodone and oxycodone during six years between 2006 and 2014, including more than 3.82 million doses in 2006 and 2007 alone.

- McKesson did not retain sufficient due diligence files documenting its relationship with Family Discount Pharmacy in Mount Gay-Shamrock during 2006 and 2007, including documentation regarding the company's apparent decision to terminate the pharmacy as a customer for "compliance reasons."

- McKesson did not consider its prior relationship with Family Discount Pharmacy when evaluating the pharmacy's new customer application in 2010, with a member of McKesson's regulatory affairs division at one point stating, "I cannot see any reason we should be hesitant" with respect to the pharmacy.

- In 2010, McKesson set the hydrocodone threshold for Family Discount Pharmacy, a pharmacy previously terminated by McKesson for compliance reasons, at a level that was 31 times higher than what the company determined warranted supplementary explanation on its new customer questionnaire.

- McKesson established a business relationship with Tug Valley Pharmacy in July 2015, despite knowledge of pending litigation against the pharmacy related to the alleged diversion of controlled substances. McKesson did not address the litigation with the pharmacy's owner while conducting its due diligence. McKesson later cited the litigation as the reason it suspended Tug Valley's ability to purchase controlled substances after the pharmacy and litigation were featured on *CBS News* in January 2016.

- In February 2016, McKesson received a new customer application from Tug Valley Pharmacy, representing that it was under new ownership. The application contained multiple

errors. McKesson also received a pharmacy questionnaire in which the new owner was unable to answer basic questions about the pharmacy.

- In February 2016, Tug Valley Pharmacy was sold through a financing arrangement under which the former owner retained a security interest in the pharmacy as collateral for making a loan to the new owner to facilitate the purchase.

- Despite McKesson policies stating that invalid, inaccurate, or inconsistent answers on a questionnaire are a cause for concern, it does not appear McKesson sought further explanation from Tug Valley Pharmacy's new owner as to why he was unable to answer several basic questions about the pharmacy as posed in McKesson's pharmacy questionnaire.

- In February 2016, Tug Valley Pharmacy's new owner told McKesson that the former owner no longer had an association with the pharmacy. Not only was this statement not true, but McKesson was in possession of a document at the time of its 2016 approval indicating that the former owner maintained a security interest in the pharmacy. The Committee has seen no indication to suggest that McKesson asked the pharmacy about the former owner's continuing security interest.

- AmerisourceBergen's due diligence documents for Westside Pharmacy included a list of six "Pain Doctors." Two of the doctors were located a four-hour and eleven-and-a-half-hour round-trip drive from the pharmacy respectively. Five of the six doctors have either been subsequently convicted of, or indicted on, criminal charges related to their controlled substance prescribing, or are currently under federal investigation.

- Based on documents provided to the Committee, in 2011, AmerisourceBergen did not investigate why Westside Pharmacy filled prescriptions for physicians located hours away from the pharmacy.

- AmerisourceBergen told the Committee that it placed stricter limits on Westside Pharmacy's purchasing of controlled substances in late 2012. The Committee received no documents that reference these limitations or the pharmacy's apparent decision to subsequently end its business relationship with AmerisourceBergen.

- AmerisourceBergen began doing business with Westside Pharmacy again in January 2016. Documents produced to the Committee give no indication to suggest that AmerisourceBergen considered the company's 2012 decision to place stricter limits on the pharmacy's ability to purchase controlled substances.

- Prior to onboarding Westside Pharmacy as a customer in January 2016, AmerisourceBergen does not appear to have consulted public news reports that would have alerted the company to red flags related to some of the pharmacy's top prescribing physicians. According to AmerisourceBergen, "[n]ews searches for prescribing physicians are not a standard part of ABDC's new customer review[.]"

- In December 2015, when Westside Pharmacy submitted a prospective customer application to AmerisourceBergen, two of the pharmacy's top prescribers of opioids were located four-hour round-trip drives from the pharmacy.

- In February 2011, H.D. Smith suspended Family Discount Pharmacy's ability to order hydrocodone, after controlled substances constituted nearly 80 percent of the pharmacy's overall purchases the month prior.

- In 2015, Family Discount Pharmacy disclosed to H.D. Smith that it had "10 days of over 1000 Rx's filled" in January 2015. The dispensing volume was despite the pharmacy's location across the street from two other pharmacies in a town of less than 2,000 people.

- When H.D. Smith onboarded Family Discount Pharmacy for a second time in 2015, the pharmacy had recently been terminated by two other wholesale distributors — with the pharmacy disclosing that one termination was based on the volume of the pharmacy's hydrocodone orders.

- Between 2007 and 2009, H.D. Smith distributed more than more than 5.65 million doses of hydrocodone to two pharmacies located approximately four blocks apart in Williamson, a town of 3,191 people.

- H.D. Smith's distribution of hydrocodone to Tug Valley Pharmacy increased more than 1,000 percent in a five-month-period in 2007, from 19,100 hydrocodone doses to 224,400 hydrocodone doses. Information H.D. Smith provided the Committee did not include documentation to justify or explain the dramatic increase in its distribution of hydrocodone to Tug Valley Pharmacy.

- H.D. Smith began implementing controlled substance thresholds for its customers, including Tug Valley Pharmacy, in 2008. The thresholds limited Tug Valley's hydrocodone purchases to under 50,000 doses a month, less than a quarter of what the pharmacy purchased in November 2007 when no thresholds were in place.

- Between 2006 and 2014, Cardinal distributed 3.71 million doses of hydrocodone to Hurley Drug Company, located in Williamson, West Virginia.

- From June 2008 to March 2011, Cardinal set Hurley Drug Company's hydrocodone threshold at 155,000, three times higher than its average monthly purchases in 2009 and 14 times higher than its average monthly purchases in 2010.

- Between June 9 and June 23, 2008, Cardinal increased the hydrocodone threshold for Hurley Drug Company on five separate occasions, culminating in a threshold of 155,000 dosages of hydrocodone a month. This was a fifteen-fold increase in the threshold in two weeks.

- Cardinal's due diligence and threshold documentation for Hurley Drug Company provides no explanation as to why any of the five hydrocodone threshold increases were made in June 2008.

- Based on documentation provided to the Committee, Hurley Drug Company did not hit its hydrocodone threshold in the approximately three years it was set at 155,000 dosage units a month.

- Cardinal did not reevaluate the threshold between June 2008 and March 2011 to determine whether it was accurately set. This includes after learning of derogatory information regarding Dr. Katherine Hoover, a doctor for whom Hurley Drug Company filled prescriptions.

- Cardinal reviewed Hurley Drug Company's account before the pharmacy's switch from a secondary to primary customer, initially anticipating that thresholds would need to be increased to accommodate growth. However, as a result of the review, Cardinal cut Hurley's hydrocodone threshold from 155,000 to 66,501 dosage units.

- Between 2006 and 2012, Cardinal Health distributed more than 6.03 million doses of hydrocodone and nearly 800,000 doses of oxycodone to Family Discount Pharmacy in Mount Gay-Shamrock, population 1,779. This amount made the pharmacy Cardinal Health's top purchaser of hydrocodone and oxycodone products in West Virginia between 2006 and 2017.

- In June 2008, Family Discount Pharmacy cited an increase in hydrocodone prescriptions written by a single doctor—Dr. Katherine Hoover—in requesting an increase to its thresholds. Based on documents provided to the Committee, Cardinal did not inquire further about Dr. Hoover's prescribing at that time and raised the hydrocodone thresholds for the pharmacy.

- In September 2008, Cardinal learned of derogatory information regarding Dr. Hoover, specifically, that two pharmacists in Kentucky would not fill prescriptions for Dr. Hoover based on concerns about her practice. Documents provided by Cardinal do not indicate the company reevaluated Family Discount Pharmacy's hydrocodone thresholds after learning of this information.

- On at least three occasions, Family Discount Pharmacy cited the closure of another pharmacy as a reason why it needed increased quantities of controlled substances. Documents provided by Cardinal do not indicate whether the company took any action to verify these claims.

- After Cardinal formed a Large Volume – Tactical and Analytical Committee, it reviewed and reduced Family Discount Pharmacy's hydrocodone threshold limit from 154,500 dosage units to 75,005 dosage units.

- In 2007, McKesson shipped an average of 9,650 hydrocodone pills a day to the Sav-Rite No. 1 pharmacy in Kermit, West Virginia. This was 36 times the threshold amount set by the Lifestyle Drug Monitoring Program.

- McKesson continued to supply Sav-Rite No. 1 with massive quantities of opioids for five months after representing to the DEA that it had reviewed all customers pursuant to the Lifestyle Drug Monitoring Program.

- McKesson supplied just under 300 million doses of hydrocodone and oxycodone to West Virginia pharmacies between April 2006 and 2016.

- McKesson did not submit suspicious order reports to the DEA regarding orders placed by West Virginia pharmacies until August 1, 2013.

- Between August 1, 2013, and December 18, 2017, McKesson submitted over 10,000 suspicious order reports to the DEA related to orders placed by West Virginia pharmacies.

- McKesson devoted "substantial resources to enhance and revise" its Controlled Substance Monitoring Program in 2013, the same year the DEA served the distributor an Administrative Inspection Warrant and an Administrative Subpoena to obtain records from its Aurora, Colorado distribution facility.

- Cardinal was West Virginia's largest supplier of oxycodone and hydrocodone between 2005 and 2016, distributing approximately 366 million doses during that time.

- Cardinal did not have a consolidated suspicious order reporting system in place until 2012 and was unable to produce comprehensive suspicious order reports regarding West Virginia pharmacies prior to 2012.

- Since 2008, Cardinal's policies have required notification of DEA regarding suspicious orders. The company was unable to provide comprehensive data prior to 2012 demonstrating compliance with these reporting policies in West Virginia.

- Cardinal issued a "complete rewrite" of its Detecting and Reporting Suspicious Orders and Responding to Threshold Events policy in April 2012. This was done a month before it entered into a settlement agreement with DEA to resolve allegations the company failed to report suspicious orders.

- AmerisourceBergen distributed nearly 250 million doses of hydrocodone and oxycodone to West Virginia pharmacies between 2005 and 2016.

- In June 2007, AmerisourceBergen reached a settlement to resolve allegations it failed to maintain effective controls to prevent controlled substance diversion. A month later, the company began to block suspicious orders and submit suspicious order reports to the DEA.

Prior to July 2007, AmerisourceBergen mailed copies of suspicious order reports to the DEA on a monthly basis but did not block any orders deemed suspicious.

- The number of suspicious order reports regarding West Virginia pharmacies that AmerisourceBergen submitted to DEA and blocked from shipment ranged from a high of 792 orders in 2013 to a low of three orders in 2016.

- AmerisourceBergen responded inconsistently when pharmacies triggered repeated suspicious orders. In 2009, the company investigated and terminated its relationship with Tug Valley Pharmacy after reporting 36 suspicious orders in one month. However, AmerisourceBergen continued to supply Beckley Pharmacy for nearly a year after reporting 109 suspicious orders in five months from 2013 to 2014.

- Before providing DEA with order-specific suspicious order reports, Miami-Luken previously reported customers it stopped doing business with. Documents provided to the Committee appear to indicate the first customer termination report was made to DEA in October 2012.

- Based on documents produced to the Committee, the first order-specific suspicious order report Miami-Luken made because a pharmacy hit a monthly threshold was submitted to DEA on May 14, 2014.

- Miami-Luken provided DEA with at least two suspicious order reports in 2014, 10 in 2015, 33 in 2016, and one in 2017. The company also stopped selling controlled substances to at least 20 pharmacies.

- According to Miami-Luken's Chairman of the Board, prior to 2013, the company made "rudimentary efforts" to monitor suspicious orders and decisions on what constituted a suspicious order were made based on "one's feeling."

- Miami-Luken did not implement a functional suspicious order monitoring system until 2015.

- In 2008 and 2009, H.D. Smith submitted individual suspicious order reports to DEA for every transaction that triggered its Controlled Substance Order Monitoring Program. The company altered its practices in subsequent years, and instead of reporting individual orders, it alerted DEA when it stopped selling controlled substances to a pharmacy or identified other suspicious customer activity.

- All but one of the 393 suspicious order reports H.D. Smith submitted to the DEA in 2008 and 2009 related to orders placed by Family Discount Pharmacy, Hurley Drug Company, Sav-Rite No. 1, and Tug Valley Pharmacy.

- H.D. Smith terminated business relationships with 15 West Virginia pharmacies over compliance concerns or failure to cooperate with due diligence efforts, but only provided documentation indicating it informed DEA about six of the terminations.

- H.D. Smith's 2009 policy states that suspicious order information will be sent to DEA Headquarters and DEA field offices. The policy does not indicate the company changed its reporting procedures to focus on suspicious activity and customers rather than order-specific suspicious order reports.

- When McKesson reinstated Tug Valley Pharmacy as a customer in February 2016, the pharmacy's new owner assured McKesson that its former owner no longer had any association with the pharmacy. However, after learning in October 2017 the former owner was employed by the pharmacy, as was a pharmacist with a felony conviction related to controlled substances, McKesson did not terminate or restrict Tug Valley's ability to purchase controlled substances.

- During a November 1, 2017 conversation between McKesson's Director of Regulatory Affairs and Tug Valley's new owner, the pharmacy owner made representations about the former owner and the convicted pharmacist that McKesson did not attempt to verify until February 28, 2018.

- McKesson's February 28, 2018 site visit to Tug Valley, which resulted in the pharmacy's termination, was initiated by a third-party request, not by McKesson's own proactive due diligence.

- At various times during a ten-year period, McKesson shipped more than 8.29 million doses of opioids to two commonly owned pharmacies, located just three miles apart in rural West Virginia.

- Family Discount Pharmacy in Mount Gay-Shamrock purchased nearly five times the amount of hydrocodone from McKesson than a nearby Rite Aid Pharmacy. McKesson fulfilled the orders placed by Family Discount Pharmacy during a time when the surrounding area had "serious prescription drug abuse issues" per a local law enforcement officer.

- McKesson terminated Family Discount's Mount Gay-Shamrock pharmacy in April 2014, but did not undertake an on-site regulatory review of the co-owned Stollings location until sixteen months later. McKesson did review purchase data from the Stollings pharmacy around the time it terminated the Mount Gay-Shamrock location, however, documentation produced to the Committee regarding that review consisted of only a single page of handwritten notes.

- An H.D. Smith analysis found a single doctor prescribed more than 158,000 doses of hydrocodone dispensed by Tug Valley Pharmacy in February 2008. During the same month, a second doctor was responsible for prescribing more than 40,000 doses of hydrocodone dispensed by the pharmacy. Combined, these two doctors prescribed, and Tug Valley Pharmacy dispensed, nine times the then-monthly volume for an average retail pharmacy in rural West Virginia.

distributors, where the agency reviewed distributors' legal responsibilities under the CSA and provided updates on DEA's areas of concern and current trends related to controlled substance diversion.

The Distributor Initiative remains active at the DEA. In written testimony, submitted for a March 20, 2018 hearing before the Committee's Subcommittee on Oversight and Investigations, then-DEA Acting Administrator Robert Patterson stated that the DEA continues to work with registrants to administer the Initiative "with a goal of educating distributors on how to detect and guard against diversion activities[.]"[84]

## F. Enforcement Actions Taken by DEA

Through the educational component of the Distributor Initiative, the DEA provided individual and group guidance to distributors on their legal obligations under the CSA, but also warned distributors that failing to meet these obligations could result in the revocation of a distributor's DEA registration. Despite this guidance, however, the DEA alleged that some distributors failed to operate in accordance with the CSA. To address distributors the DEA believed were continuing to violate the CSA, the agency adopted a more aggressive enforcement posture and undertook actions to revoke their registrations.[85] In accordance with the heightened emphasis on enforcement, the DEA undertook actions to revoke the registrations of various regional and mid-size wholesale distributors including Southwood Pharmaceuticals,[86] Richie Pharmacal,[87] and Keysource Medical,[88] among others.[89]

The enforcement actions undertaken by the DEA were not limited to regional and mid-size distributors, as the agency also took action against major national wholesale distributors for alleged violations of the CSA. For example, on August 4, 2006, the DEA issued an OTSC against McKesson, seeking to revoke the DEA registration for the company's Lakeland, Florida

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[84] *The Drug Enforcement Administration's Role in Combating the Opioid Epidemic: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. at 6 (2018) (statement of Robert Patterson, Acting Adm'r, U.S. Drug Enforcement Admin.) *available at* https://docs.house.gov/meetings/IF/IF02/20180320/108026/HHRG-115-IF02-Wstate-PattersonR-20180320.pdf.

[85] *See Responding to the Prescription Drug Abuse Epidemic: Hearing Before S. Caucus on Int'l Narcotics Control*, 112th Cong., 9-10 (2012) (statement of Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin.) *available at* https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/07/18/12/07-18-12-dea-rannazzisi.pdf.

[86] *See* 72 Fed. Reg. 36,487, July 3, 2007.

[87] *See In re Richie Pharmacal*, Memorandum of Agreement (Aug. 7, 2007) *available at* https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20Richie%20Pharmaceutical%20-%202007.pdf.

[88] *See* Press Release, U.S. Drug Enforcement Admin., Cincinnati Pharmaceutical Supplier's DEA License Suspended (June 10, 2011) *available at* https://www.dea.gov/press-releases/2011/06/10/cincinnati-pharmaceutical-suppliers-dea-license-suspended.

[89] *See* Lenny Bernstein, David S. Fallis, and Scott Higham, *How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job,'* WASH. POST, Oct. 22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.0cbc79264365.

distribution facility.[90] The DEA issued a second OTSC against McKesson on November 1, 2007, this time seeking to revoke the DEA registration for the company's distribution facility in Landover, Maryland.[91] To resolve these allegations, McKesson reached a settlement with the DEA on May 2, 2008, wherein the company, among other things, agreed to pay a $13.25 million fine, and be subject to heightened reporting requirements.[92] On January 17, 2017, McKesson entered into another settlement with the DEA, which stated that, at various times, it did not abide by the terms of the 2008 settlement agreement, and that it failed to maintain effective controls against diversion at 12 separate distribution facilities across the country, approximately one-third of the company's distribution facilities overall.[93] McKesson agreed to pay a $150 million fine, and to temporarily suspend distributing controlled substances at four of its distribution facilities, among other obligations. Unlike 2008, there was no precipitating OTSC associated with the 2017 settlement.[94]

The DEA also initiated enforcement actions against AmerisourceBergen and Cardinal Health for their alleged failures to comply with the CSA. On April 19, 2007, the DEA issued an ISO and OTSC against AmerisourceBergen, seeking to revoke the DEA registration of the company's Orlando, Florida distribution facility for its alleged failure to maintain effective controls against diversion and report suspicious orders to the DEA.[95] The DEA and AmerisourceBergen entered into a settlement agreement to resolve the DEA's allegations on June 22, 2007, wherein the company agreed to be subject to heightened reporting requirements; AmerisourceBergen did not pay a fine in connection with this settlement.[96]

Between November 28, 2007 and January 30, 2008, the DEA brought four enforcement actions to revoke the registrations of Cardinal Health's distribution facilities in Washington, Florida, New Jersey, and Texas, alleging that Cardinal failed to meet its legal obligations under the CSA at each of these facilities.[97] The DEA and Cardinal entered into a settlement agreement

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[90] *In re McKesson*, Settlement and Release Agreement and Administrative Memorandum of Agreement, May 2, 2008 (On file with Committee).

[91] *Id.*

[92] *Id.* In the May 2, 2008 settlement agreement, the DEA also alleged that McKesson failed to maintain effective controls against diversion at its Conroe, Texas and Denver, Colorado distribution facilities.

[93] *See In re McKesson*, Settlement Agreement and Release, Jan. 17, 2017, *available at* https://www.justice.gov/opa/press-release/file/928471/download; *see also In re McKesson*, Administrative Memorandum of Agreement, Jan. 17, 2017, *available at* https://www.justice.gov/opa/press-release/file/928476/download, and Lenny Bernstein and Scott Higham, *'We feel like our system was hijacked': DEA agents say a huge opioid case ended in a whimper*, WASH. POST, Dec. 17, 2017, https://www.washingtonpost.com/investigations/mckesson-dea-opioids-fine/2017/12/14/ab50ad0e-db5b-11e7-b1a8-62589434a581_story.html?utm_term=.b0e352a571e5.

[94] *See In re McKesson*, Settlement Agreement and Release, Jan. 17, 2017, *available at* https://www.justice.gov/opa/press-release/file/928471/download. *See also In re McKesson*, Administrative Memorandum of Agreement, Jan. 17, 2017, *available at* https://www.justice.gov/opa/press-release/file/928476/download.

[95] *In re AmerisourceBergen*, Settlement and Release Agreement (June 22, 2007) (On file with Committee).

[96] *Id.*

[97] *See* U.S. Drug Enforcement Admin., *In re Cardinal Health*, Order to Show Cause and Immediate Suspension of Registration, Nov. 28, 2007 (On file with Committee); U.S. Drug Enforcement Admin., *In re Cardinal Health*, Order to Show Cause and Immediate Suspension of Registration, Dec. 5, 2007 (On file with Committee); U.S. Drug Enforcement Admin., *In re Cardinal Health*, Order to Show Cause and Immediate Suspension of Registration, Dec.

on October 2, 2008 to resolve the allegations, wherein Cardinal agreed to heightened reporting requirements and to pay a $34 million fine to the federal government.[98] However, on February 2, 2012, the DEA issued an ISO and OTSC against Cardinal, seeking to revoke the DEA registration of the company's distribution facility in Lakeland, Florida, alleging that Cardinal failed to abide by the terms of the 2008 settlement, and that its distribution practices continued to be in violation of the CSA.[99] Cardinal and the DEA entered into another settlement to resolve these allegations on May 14, 2012,[100] with the company once again agreeing to pay a $34 million dollar penalty.[101]

However, as will be discussed in greater detail later in this report, the number of ISOs initiated by the DEA began to substantially decline in 2013, with the agency failing to bring any ISOs against distributors for nearly a six-year period. On May 2, 2018, the DEA issued an ISO against Morris & Dickson Company, a Louisiana-based wholesale distributor, alleging the company failed to maintain effective controls against diversion, and report suspicious orders to the DEA in relation to the company's sales to several high-volume pharmacies in Louisiana.[102] This was the first ISO issued by the DEA against a wholesale distributor since 2012.[103] However, the DEA rescinded the ISO against Morris & Dickson Company on May 18, 2018, after a federal judge granted a motion brought by the company, enjoining the ISO from being enforced.[104] The rescission of the ISO notwithstanding, Morris & Dickson Company's DEA registration may ultimately still be revoked as the DEA also issued an OTSC against the company, which would revoke the company's DEA registration if the DEA's Administrator determines, after considering all available evidence, that doing so is consistent with the public's interest.[105] The DEA has indicated to the Committee that it is currently in pre-hearing

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7, 2007 (On file with Committee); and U.S. Drug Enforcement Admin., *In re Cardinal Health*, Order to Show Cause, Jan. 30, 2008 (On file with Committee).

[98] *In re Cardinal Health*, Settlement and Release Agreement and Administrative Memorandum of Agreement, Oct. 2, 2008, (On file with Committee). In the settlement, the DEA alleged that Cardinal also failed to maintain effective controls against diversion at distribution facilities located in California, Colorado, and Georgia.

[99] *See* U.S. Drug Enforcement Admin., *In re Cardinal Health*, Order to Show Cause and Immediate Suspension of Registration, Feb. 2, 2012, (On file with Committee).

[100] *In re Cardinal Health*, Administrative Memorandum of Agreement, May 14, 2012, (On file with Committee).

[101] Press Release, U.S. Dep't of Justice, M.D. Fla., United States Reaches $34 Million Settlement With Cardinal Health For Civil Penalties Under the Controlled Substances Act (Dec. 23, 2016) *available at* https://www.justice.gov/usao-mdfl/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under.

[102] Press Release, U.S. Dep't of Justice, DEA Suspends the Registration of Morris & Dickson Company from Distributing Controlled Substances (May 4, 2018) *available at* https://www.justice.gov/opa/pr/dea-suspends-registration-morris-dickson-company-distributing-controlled-substances.

[103] Lenny Bernstein and Sari Horwitz, *DEA issues first immediate suspension of opioid sales to a wholesaler since 2012*, WASH. POST, May 4, 2018, https://www.washingtonpost.com/national/health-science/dea-issues-first-immediate-suspension-of-opioid-sales-to-a-wholesaler-since-2012/2018/05/04/660f53be-4fe4-11e8-84a0-458a1aa9ac0a_story.html?utm_term=.a0a203172b0e.

[104] Sari Horwitz and Scott Higham, *Justice Department rescinds order stopping opioid sales by Louisiana distributor*, WASH. POST, May 18, 2018, https://www.washingtonpost.com/world/national-security/justice-department-rescinds-order-stopping-opioid-sales-by-louisiana-distributor/2018/05/18/d90eee46-5abc-11e8-8836-a4a123c359ab_story.html?utm_term=.56839c5d6911.

[105] Nick Wooten, *Morris & Dickson still faces DEA hearing over opioid orders*, SHREVEPORT TIMES, May 21, 2018, https://www.shreveporttimes.com/story/news/2018/05/21/morris-dickson-still-faces-federal-hearing-over-opioid-orders/629936002/.

## A. Prospective Customer Due Diligence Efforts by the Distributors

### 1. The Legal Framework and Distributor Policies Regarding Prospective Customer Due Diligence

The CSA requires that wholesale distributors "[maintain] effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels[.]"[383] In addition, federal regulations require, "[a]ll [DEA] applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances."[384] These statutory and regulatory requirements have been interpreted as requiring, among other things, that distributors conduct adequate due diligence of their customers to mitigate against the potential diversion of controlled substances. For example, in 2007, the DEA Deputy Administrator issued a final order revoking the registration of Southwood Pharmaceuticals, a California-based wholesale distributor, for, among other things, the company's failure to conduct adequate due diligence of its prospective and existing customers.[385] In the final order the Deputy Administrator noted, "[i]n short, the direct and foreseeable consequence of the manner in which Respondent conducted its due diligence program was the likely diversion of millions of dosage units of hydrocodone."[386]

In September 2006 and February 2007, the DEA sent two identical letters to "every commercial entity in the United States registered with the [DEA] to distribute controlled substances" in which the agency reiterated the statutory obligation that distributors maintain effective controls against diversion, as well as the regulatory requirement to report suspicious orders.[387] In each letter, the DEA wrote:

> It bears emphasis that the foregoing reporting requirement[388] is in addition to, and not in lieu of, the general requirement under 21 U.S.C. 823(e) that a distributor maintain effective controls against diversion.
>
> Thus, in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels. Failure to exercise such due diligence could, as

[383] 21 U.S.C. § 823(b) and 21 U.S.C. § 823(e).
[384] 21 C.F.R. § 1301.71(a).
[385] *See* 72 Fed. Reg. 36,487, July 3, 2007.
[386] 72 Fed. Reg. 36,500, July 3, 2007.
[387] Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin., to DEA Registrants, Sept. 27, 2006 (On file with Committee); Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin., to DEA Registrants, Feb. 7, 2007 (On file with Committee).
[388] Here, the letters reference suspicious order reporting regulations, promulgated at 21 C.F.R. § 1301.74(b), which states, "[t]he registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

> circumstances warrant, provide a statutory basis for revocation or suspension of a distributor's registration.
>
> In a similar vein, given the requirement under section 823(e) that a distributor maintain effective controls against diversion, a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances.[389]

In September 2015, the DEA Acting Administrator issued a final order revoking the DEA registration of Masters Pharmaceuticals, a Cincinnati, Ohio-based wholesale distributor for the company's failure to conduct adequate due diligence, and report suspicious orders to the DEA.[390] In the final order, the Acting Administrator also referenced and quoted the aforementioned DEA letters[391] in addition to reiterating a distributor's obligation to conduct due diligence on prospective and existing customers, stating:

> As *Southwood* makes clear, a distributor's duty to perform due diligence on its customers stems from the requirement that a registrant "shall provide effective controls and procedures to guard against theft and diversion of controlled substances," 21 CFR 1301.71(a), as well as the registration requirements of section 823, which, in the case of a distributor, direct the Agency, in making the public interest determination, to consider the "maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical . . . channels." 21 U.S.C 823(b); *see also id.* §823(e). As for the scope of the duty to perform due diligence, *Southwood* makes clear that doing "nothing more than verifying a pharmacy's DEA registration and state license" is not enough. 72 FR 36,498. Rather, a distributor must conduct a reasonable investigation "to determine the nature of a potential customer's business before it" sells to the customer, and the distributor cannot ignore "information which raise[s] serious doubt as to the legality of [a potential or existing customer's] business practices."[392]

The Acting Administrator also stated in the *Masters* order that "depending upon the circumstances, a distributor may need to perform site visits before it engages in any distribution of controlled substances. Moreover, the obligation to perform due diligence is ongoing throughout the course of a distributor's relationship with its customer."[393] In the final order, the Acting Administrator referenced that, in certain circumstances, the company failed to seek further explanation when presented with information that conflicted with what was provided

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[389] Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin., to DEA Registrants, Sept. 27, 2006 (On file with Committee); Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin., to DEA Registrants, Feb. 7, 2007 (On file with Committee).
[390] *See* 80 Fed. Reg. 55,418, Sept. 15, 2015.
[391] 80 Fed. Reg. 55,421, Sept. 15, 2015.
[392] 80 Fed. Reg. 55,477, Sept. 15, 2015 (quoting 72 Fed. Reg. 36,498, July 3, 2007).
[393] 80 Fed. Reg. 55,477, Sept. 15, 2015.

during the due diligence process, leading the Acting Administrator to suggest the company's "purpose in asking these questions was simply to go through the motion of conducting due diligence."[394] The Acting Administrator also faulted the company for not performing additional due diligence when it was presented with factors suggestive of possible diversion, such as a pharmacy being co-located with a clinic,[395] or dispensing high percentages of controlled substances.[396]

In the course of this investigation, the Committee requested and received information from distributors regarding their due diligence process. These documents included prospective customer forms, policies and procedures related to onboarding customers, and due diligence files on specified pharmacies. The information reviewed by the Committee raises concerns about the adequacy of the distributors' due diligence efforts at times during the time period covered by the Committee's investigation.

While the DEA has interpreted the CSA and federal regulations as requiring distributors to, among other things, conduct adequate due diligence of prospective and existing customers, neither the agency nor federal regulations require that distributors adopt any particular approach to satisfy this legal obligation. By reviewing the material obtained during the course of its investigation, the Committee was able to gain a better understanding of how distributors conducted due diligence of prospective customers.[397]

Based upon the Committee's review, the majority of the distributors that were the focus of the Committee's investigation updated their policies and procedures related to prospective customer due diligence between 2007 and 2008, generally requiring, at a minimum, the completion of a prospective customer questionnaire which would be reviewed prior to onboarding a pharmacy. These distributors have, at various times, updated their policies for conducting prospective customer due diligence.

In general, distributors' prospective customer questionnaires are completed by the pharmacy and provide distributors with background information with respect to the pharmacy as well as its anticipated ordering habits. For example, in the questionnaires prospective customers are generally required to disclose:

- DEA and state board of pharmacy licensure information for the pharmacy and its staff;
- Whether the pharmacy or its staff have ever been subject to discipline by the DEA or relevant state authorities;
- Whether the pharmacy fills prescriptions that were obtained over the internet;

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[394] 80 Fed. Reg. 55,488, fn. 179, Sept. 15, 2015.
[395] 80 Fed. Reg. 55,498, Sept. 15, 2015.
[396] 80 Fed. Reg. 55,495, Sept. 15, 2015.
[397] For purposes of this discussion, the term 'prospective customer' includes both pharmacies that are requesting to do business with a wholesale distributor for the first time as well pharmacies that had a prior relationship with a distributor and are requesting to reestablish any such relationship.

- Whether the pharmacy had its ability to purchase controlled substances restricted or terminated by a distributor in the past;

- Estimates regarding what percentage of the pharmacy's prescriptions are paid for by private insurance, by Medicare/Medicaid, or in cash, among other information; and

- Estimates regarding what percentage of a pharmacy's overall sales are attributable to controlled substances.

When conducting due diligence, a distributor may obtain information about a pharmacy's prescribing physicians, such as by asking a pharmacy to disclose this on a new customer questionnaire. Receiving such information enables a distributor to conduct analysis on the top prescribing physicians and enhances a distributor's ability to identify possible red flags of diversion. For example, if a distributor is provided with a pharmacy's prescribing physicians, it can then search the internet for any concerning news articles involving these physicians, in addition to any disciplinary actions that may have been taken by state medical boards. Obtaining a pharmacy's prescribing physicians also enables a distributor to identify whether a pharmacy is filling prescriptions of any physicians who may be located substantial distances from the pharmacy, which the DEA has cited as being a red flag for diversion.[398]

Prospective customer questionnaires also generally require pharmacies to provide estimated dispensing figures for certain controlled substances, with some distributors requiring pharmacies to submit dispensing reports in addition to the prospective customer questionnaire. Obtaining a dispensing report provides a distributor with the ability to see the total volume of controlled substances dispensed by a pharmacy over a given period of time. The dispensing reports obtained by distributors may be de-identified, providing aggregated dispensing information but not identifying the physicians whose prescriptions were filled by the pharmacy. An example of this type of dispensing report is reproduced below:[399]

[398] *See* 80 Fed. Reg. 5 5,491, Sept. 15, 2015.
[399] McKesson Corp., Family Discount Pharmacy (Mount Gay-Shamrock) Dispensing Report 2/23/12 to 8/23/12 (On file with Committee).

FAMILY DISCOUNT PHARMACY
Old Route 119
Mt. Gay, WV 25637
[redacted] Fax: [redacted]

UTILIZATION
Period 2/23/12 to 8/23/12
Thu Aug 23, 2012

Page 21
PID: [redacted]
NPI: [redacted]

| Rank | Drug Name | NDC | Rxs | Rfs | Qty | Total U&C | Total Price | Total Cost | Gross Margin | % Margin |
|---|---|---|---|---|---|---|---|---|---|---|
| 881 | HALOPERIDOL 1MG | 0378-0257-10 | 1 | 0 | 90 | [redacted] | | | | |
| 882 | HALOPERIDOL 20 MG TABLET | 68382-081-01 | 2 | 4 | 720 | | | | | |
| 883 | HALOPERIDOL 5MG | 0378-0327-10 | 4 | 5 | 261 | | | | | |
| 884 | HALOPERIDOL DEC 100 MG/ML | 10147-0922-5 | 2 | 5 | 7 | | | | | |
| 885 | HECTOROL 1 MCG CAPSULE | 58468-0124-1 | 1 | 5 | 210 | | | | | |
| 886 | HEPARIN LOCK FLUSH 100 UN | 63323-545-05 | 1 | 0 | 5 | | | | | |
| 887 | HEPARIN LOCK FLUSH 100UNI | 0409-1152-70 | 0 | 1 | 10 | | | | | |
| 888 | HOMATROPAIRE 5% EYE DROPS | 59390-0192-05 | 2 | 0 | 10 | | | | | |
| 889 | HUGGIES SNUG & DRY STEP 5 | 36000-55395 | 3 | 4 | 1750 | | | | | |
| 890 | HUGGIES SNUG & DRY STEP 6 | 36000-55506 | 1 | 8 | 1550 | | | | | |
| 891 | HUMALOG | 0002-7510-01 | 15 | 12 | 390 | | | | | |
| 892 | HUMALOG 100 UNITS/ML CART | 0002-7516-59 | 0 | 3 | 90 | | | | | |
| 893 | HUMALOG KWIKPEN 15ML | 0002-8799-59 | 30 | 31 | 965 | | | | | |
| 894 | HUMALOG MIX 50/50 | 0002-7512-01 | 1 | 3 | 240 | | | | | |
| 895 | HUMALOG MIX 75-25 KWIKPEN | 0002-8797-59 | 4 | 6 | 270 | | | | | |
| 896 | HUMALOG MIX 75/25 10ML | 0002-7511-01 | 16 | 52 | 2700 | | | | | |
| 897 | HUMIRA 40MG/0.8ML SYRINGE | 0074-3799-02 | 4 | 10 | 28 | | | | | |
| 898 | HUMULIN 70/30 INSULIN | 0002-8715-01 | 9 | 5 | 370 | | | | | |
| 899 | HUMULIN N PEN | 0002-8730-59 | 9 | 11 | 390 | | | | | |
| 900 | HUMULIN N U100 VIAL 10ML | 0002-8315-01 | 15 | 16 | 640 | | | | | |
| 901 | HUMULIN R U-500 VIAL 20ML | 0002-8501-01 | 0 | 3 | 100 | | | | | |
| 902 | HUMULIN R U100 VIAL 10ML | 0002-8215-01 | 1 | 2 | 30 | | | | | |
| 903 | HYALGAN 20 MG/2 ML SYRING | 89122-0724-20 | 1 | 0 | 6 | | | | | |
| 904 | HYDRALAZINE 10 MG TABLET | 23155-001-01 | 4 | 3 | 630 | | | | | |
| 905 | HYDRALAZINE 100 MG TABLET | 23155-004-01 | 1 | 5 | 720 | | | | | |
| 906 | HYDRALAZINE 25 MG TABLET | 23155-002-10 | 17 | 25 | 3630 | | | | | |
| 907 | HYDRALAZINE 50 MG TABLET | 23155-003-01 | 5 | 12 | 1260 | | | | | |
| 908 | HYDROCHLOROTHIAZIDE 12.5 | 23155-045-05 | 66 | 95 | 5918 | | | | | |
| 909 | HYDROCHLOROTHIAZIDE 25 MG | 0603-3856-34 | 132 | 168 | 9481 | | | | | |
| 910 | HYDROCHLOROTHIAZIDE 50MG | 0603-3857-32 | 7 | 22 | 1110 | | | | | |
| 911 | HYDROCOD/BITART/ACETAM 10 | 0603-3886-28 | 83 | 60 | 12801 | | | | | |
| 912 | HYDROCODON-APAP 10-325 | 0603-3807-32 | 138 | 110 | 25409 | | | | | |
| 913 | HYDROCODON-APAP 10-500 | 0406-0363-05 | 1657 | 1167 | 211568 | | | | | |

Distributors also have the ability to obtain dispensing information from pharmacies that not only shows the volume of controlled substances a pharmacy dispenses over a given period of time, but also identifies the physicians associated with each prescription that is filled by a pharmacy.[400] This enables a distributor to identify whether any physicians are responsible for writing a disproportionate percentage of the prescriptions filled by the pharmacy, which the DEA has also identified as being a red flag for diversion,[401] in addition to being able to assess a pharmacy's overall dispensing volume. An example of this type of dispensing report is reproduced below:[402]

[400] The distributors' policies regarding obtaining dispensing data are discussed later in this section.
[401] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin., to DEA Registrants, Sept. 27, 2006 (On file with Committee); Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin., to DEA Registrants, Feb. 7, 2007 (On file with Committee).
[402] H.D. Smith Wholesale Drug. Co., Westside Pharmacy Dispensing Report 6/1/2010 to 6/30/2010 (On file with Committee).

*Rx Register Brief-Landscape* **DRUG REPORT**
**WESTSIDE PHARMACY**

**FROM: 06/01/2010 THROUGH: 06/30/2010**

| RX# | DATE | PATIENT | ITEM | QTYD | PRESCRIBER | DISP COST | TOT ADJ AMT | PAT PAY | PRIM CVG |
|---|---|---|---|---|---|---|---|---|---|
| N 299656 | 06/14/2010 | | OXYCODONE 15MG TAB | 21.00 | KOSTENKO, MICHAEL | | | | CASH |
| N 301917 | 06/14/2010 | | OXYCODONE 15MG TAB | 35.00 | KOSTENKO, MICHAEL | | | | CASH |
| N 301952 | 06/14/2010 | | OXYCODONE 15MG TAB | 112.00 | KOSTENKO, MICHAEL | | | | CASH |
| N 302009 | 06/14/2010 | | OXYCODONE 15MG TAB | 112.00 | KOSTENKO, MICHAEL | | | | CASH |
| N 302013 | 06/14/2010 | | OXYCODONE 15MG TAB | 84.00 | KOSTENKO, MICHAEL | | | | CASH |
| N 302043 | 06/14/2010 | | OXYCODONE 15MG TAB | 84.00 | [redacted] | | | | CASH |
| N 302029 | 06/15/2010 | | OXYCODONE 15MG TAB | 180.00 | DERAKHSHAN, I MD | | | | MEDCO |
| N 302132 | 06/15/2010 | | OXYCODONE 15MG TAB | 45.00 | KOSTENKO, MICHAEL | | | | CASH |
| N 302136 | 06/15/2010 | | OXYCODONE 15MG TAB | 21.00 | KOSTENKO, MICHAEL | | | | CASH |
| N 302278 | 06/15/2010 | | OXYCODONE 15MG TAB | 120.00 | KOSTENKO, MICHAEL | | | | ADV |
| N 302313 | 06/15/2010 | | OXYCODONE 15MG TAB | 112.00 | MORGAN, DAVID MD | | | | CASH |
| N 302349 | 06/16/2010 | | OXYCODONE 15MG TAB | 84.00 | KOSTENKO, MICHAEL | | | | CASH |
| N 302361 | 06/16/2010 | | OXYCODONE 15MG TAB | 84.00 | KOSTENKO, MICHAEL | | | | CASH |
| N 302363 | 06/16/2010 | | OXYCODONE 15MG TAB | 28.00 | KOSTENKO, MICHAEL | | | | CASH |
| N 302417 | 06/16/2010 | | OXYCODONE 15MG TAB | 84.00 | KOSTENKO, MICHAEL | | | | WEST |
| N 302450 | 06/16/2010 | | OXYCODONE 15MG TAB | 70.00 | KOSTENKO, MICHAEL | | | | CASH |
| N 299396 | 06/17/2010 | | OXYCODONE 15MG TAB | 28.00 | KOSTENKO, MICHAEL | | | | CASH |
| N 302539 | 06/17/2010 | | OXYCODONE 15MG TAB | 120.00 | MORGAN, DAVID MD | | | | CASH |
| R 302539 | 06/17/2010 | | OXYCODONE 15MG TAB | 120.00 | MORGAN, DAVID MD | | | | WVM |
| N 302541 | 06/17/2010 | | OXYCODONE 15MG TAB | 120.00 | MORGAN, DAVID MD | | | | WVM |
| R 302541 | 06/17/2010 | | OXYCODONE 15MG TAB | 120.00 | MORGAN, DAVID MD | | | | CASH |
| N 302591 | 06/17/2010 | | OXYCODONE 15MG TAB | 168.00 | MORGAN, DAVID MD | | | | CCCRX |
| N 302636 | 06/17/2010 | | OXYCODONE 15MG TAB | 90.00 | KOSTENKO, MICHAEL | | | | CASH |
| N 302637 | 06/17/2010 | | OXYCODONE 15MG TAB | 56.00 | KOSTENKO, MICHAEL | | | | CASH |
| N 302836 | 06/19/2010 | | OXYCODONE 15MG TAB | 84.00 | KOSTENKO, MICHAEL | | | | ADV |
| N 302907 | 06/20/2010 | | OXYCODONE 15MG TAB | 56.00 | KOSTENKO, MICHAEL | | | | MSC |
| N 302835 | 06/21/2010 | | OXYCODONE 15MG TAB | 35.00 | KOSTENKO, MICHAEL | | | | CASH |
| N 303119 | 06/22/2010 | | OXYCODONE 15MG TAB | 21.00 | KOSTENKO, MICHAEL | | | | CASH |
| N 303243 | 06/22/2010 | | OXYCODONE 15MG TAB | 112.00 | KOSTENKO, MICHAEL | | | | CASH |
| N 303246 | 06/22/2010 | | OXYCODONE 15MG TAB | 90.00 | KOSTENKO, MICHAEL | | | | ANT |
| N 303299 | 06/22/2010 | | OXYCODONE 15MG TAB | 84.00 | KOSTENKO, MICHAEL | | | | CASH |
| N 303340 | 06/23/2010 | | OXYCODONE 15MG TAB | 28.00 | KOSTENKO, MICHAEL | | | | CASH |
| N 303359 | 06/23/2010 | | OXYCODONE 15MG TAB | 60.00 | GEORGESCU, VICTOR | | | | CCCRX |
| N 303452 | 06/23/2010 | | OXYCODONE 15MG TAB | 180.00 | GEORGESCU, VICTOR | | | | EXP |
| N 303569 | 06/23/2010 | | OXYCODONE 15MG TAB | 150.00 | MORGAN, DAVID MD | | | | CASH |
| N 303474 | 06/24/2010 | | OXYCODONE 15MG TAB | 21.00 | KOSTENKO, MICHAEL | | | | CASH |

Obtaining dispensing information that identifies prescribing physicians also ensures that a distributor is not solely relying on a pharmacy to self-disclose its top prescribing physicians and methods of payment on a new customer questionnaire.

**FINDING: Distributors can obtain dispensing data from pharmacies that shows the total volume of controlled substances dispensed by a pharmacy, including the method of payment and physician associated with each prescription.**

Distributors may also conduct on-site pharmacy visits as part of their prospective customer due diligence efforts, where the information provided on the prospective customer questionnaire may be reviewed. Conducting an onsite visit also provides a distributor with the ability to make general observations about a pharmacy as well as its surrounding area, including

the presence of any other pharmacies that may be located in close proximity to the prospective customer which is especially relevant if a prospective customer dispenses, or estimates to dispense, a large volume of controlled substances.

*a. AmerisourceBergen's Approach to Prospective Customer Due Diligence*

AmerisourceBergen developed its process for evaluating prospective customers in 2007.[403] That year, AmerisourceBergen entered into a settlement agreement with the DEA to resolve allegations brought by the agency, in which the company agreed, among other things, "to maintain a compliance program designed to detect and prevent diversion of controlled substances[.]"[404] With respect to the company's approach to prospective customer due diligence, Mr. Collis testified:

> AmerisourceBergen Drug Corporation's diversion control team performs due diligence to determine whether prospective new customers are suitable purchasers of controlled substances. The procedure to review prospective customers has varied over time but since 2007 has generally included the following elements: the completion of a Retail Customer Questionnaire; site visits; verification of the pharmacy's DEA registration and state licensure; review of the pharmacy-provided information; and online investigation (including internet licensing and disciplinary searches) for the identified pharmacy, owner, and pharmacist-in-charge. The questions on the questionnaire are based on guidance from the DEA.[405]

Regarding the prospective customer questionnaire, the company told the Committee:

> The information contained on the questionnaire is the basis for ABDC's due diligence investigation and provides a baseline to measure the pharmacy's ordering habits and to determine any deviation from expected purchasing practices. The questionnaire provides information to ABDC regarding anticipated ordering practices, including, among other things, the amount of controlled substances ordered, the anticipated ratio of controlled vs. non-controlled substances purchased, key prescribing doctors in the area utilizing the pharmacy, the purchasing practices of the pharmacy's customers (*i.e.* cash, credit, insurance, etc.), and whether another supplier is known to have suspended or ceased controlled substance sales to the

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[403] *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. 7 (2018) (testimony of Steven H. Collis, CEO, President and Chairman of the Board, AmerisourceBergen Corp.) *available at* https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Wstate-CollisS-20180508.pdf.
[404] *In re AmerisourceBergen*, Settlement and Release Agreement, 2 (June 22, 2007) (On file with Committee).
[405] *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. 7 (2018) (testimony of Steven H. Collis, CEO, President and Chairman of the Board, AmerisourceBergen Corp.) *available at* https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Wstate-CollisS-20180508.pdf.

> customer. The questionnaire also includes inquiries on topics such as high-risk drugs and high-prescribing physicians.[406]

Based on information provided to the Committee, AmerisourceBergen does not appear to require prospective customers to provide dispensing data as part of their application, unless specifically requested to do so by the company. In response to a question posed after the Subcommittee's May 8, 2018 hearing regarding whether the company requests dispensing data from its prospective and existing customers, AmerisourceBergen told the Committee, "ABDC does, at times, request dispensing data from both current and prospective customers. There is no specific frequency at which dispensing data is requested from customers."[407]

AmerisourceBergen later told the Committee, "ABDC collects patient de-identified dispensing reports on an as-needed basis to allow it to investigate and mitigate concerns about possible suspicious behavior by its customers[,]" and that "[c]ustomers may also be asked to provide full dispensing reports as part of new customer due diligence, again to mitigate red flags discovered during onboarding or to properly size the pharmacy as part of the company's Ordering Monitoring Program."[408] The company also added:

> Collecting dispensing data on a routine basis from all pharmacies is not a requirement that is imposed upon the distributor by the governing federal laws and implementing regulations. The main purpose of collecting and reviewing dispensing data is to identify potential inappropriate patient dispensing at the pharmacy. It is well established that the "corresponding responsibility" to ensure the clinical appropriateness of a prescription falls on the practitioner who supplied the prescription as well as the pharmacist who fills the prescription. Requiring distributors, like ABDC, to collect dispensing data from all DEA registrants without cause effectively transfers [the] pharmacist's responsibilities for diversion control onto the distributor, a role the distributor should not have.[409]

AmerisourceBergen did say, however, "[w]hen dispensing data is requested, ABDC does generally request that its customers provide the data in a manner that allows for the identification of prescribing physicians."[410]

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[406] Letter from Counsel to AmerisourceBergen Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., June 30, 2017 (On file with Committee).
[407] *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (2018) (Responses to Questions for the Record submitted by Steven H. Collis, CEO, President and Chairman of the Board, AmerisourceBergen Corp.).
[408] E-Mail from Counsel to AmerisourceBergen Corp., to Staff, H. Comm. on Energy and Commerce (Aug. 17, 2018 4:46 pm) (On file with Committee).
[409] *Id.*
[410] *Id.*

### b. *Cardinal Health's Approach to Prospective Customer Due Diligence*

Cardinal Health told the Committee that after it received the DEA's February 7, 2007 letter, the company "worked to ensure its systems complied with DEA's new statements with respect to suspicious order monitoring and reporting."[411] In its response to the Committee, the company also added:

> In 2007, Cardinal Health began requiring completion of a New Pharmacy Questionnaire as part of the account approval process for all new retail independent pharmacies. The questionnaire collected general information about the pharmacy, its owner, and the pharmacist in charge; general information about the pharmacy's other suppliers; information about the pharmacy's customers and their primary method of payment for controlled and non-controlled substances; and the pharmacy's expected controlled substance ordering, among other information. Cardinal Health employees vetted these questionnaires, and conducted additional investigation where appropriate.[412]

Thereafter, in December 2008, Cardinal implemented formal anti-diversion Standard Operating Procedures (SOPs), which included SOPs for conducting prospective customer due diligence.[413] That same year, Cardinal entered into a settlement agreement with the DEA to resolve allegations brought by the agency, agreeing, among other things, "to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations."[414] Since 2008, the SOPs have undergone a number of revisions, including in 2017.[415]

Pursuant to the 2017 SOPs, upon receiving a prospective customer questionnaire, Cardinal's Corporate Anti-Diversion New Account Set-up team validates "that the customer is eligible to be reviewed for purchasing controlled substances from Cardinal Health."[416] The Corporate Anti-Diversion New Account Set-up team will then review the information the pharmacy provided on the prospective customer questionnaire, requesting additional information or further review, if necessary.[417]

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[411] Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Apr. 25, 2018 (On file with Committee).
[412] *Id.*
[413] *See* Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Apr. 25, 2018 (On file with Committee); *See also* Cardinal Health, Inc., Standard Operating Procedures – New Account Approval (initial release of new procedure Dec. 22, 2008) (On file with Committee).
[414] *In re Cardinal Health,* Settlement and Release Agreement and Administrative Memorandum of Agreement, Oct. 2, 2008, 3 (On file with Committee).
[415] *See* Letter from Counsel to Cardinal Health, Inc., to Staff, H. Comm. on Energy and Commerce, Apr. 25, 2018 (On file with Committee).
[416] Cardinal Health, Inc., Standard Operating Procedure – New Account Approval (Effective Date – Jan. 6, 2017) (On file with Committee).
[417] *Id.*

Based on information provided to the Committee, Cardinal Health does not appear to require prospective customers to provide dispensing data as part of their application, unless specifically requested to do so by the company. In response to a question posed after the Subcommittee's May 8, 2018 hearing regarding whether the company requests dispensing data from its prospective and existing customers, Cardinal told the Committee:

> As part of its comprehensive anti-diversion program, Cardinal Health periodically requests and receives aggregate dispensing data and total number of prescriptions filled for both controlled and non-controlled substances from prospective and existing pharmacy customers. Cardinal Health requests total number of prescriptions filled for certain controlled substances from prospective customers as part of its initial Know Your Customer account set up process.[418]

Cardinal added that it will not distribute opioids to a pharmacy if it refuses to provide the company with dispensing data upon request.[419]

### c. *McKesson's Approach to Prospective Customer Due Diligence*

McKesson administers prospective customer due diligence as part of its larger Controlled Substances Monitoring Program (CSMP).[420] According to McKesson, the CSMP was developed during the period the company was engaged in negotiations with the DEA, ultimately leading to the settlement that was finalized on May 2, 2008.[421] Documents produced to the Committee indicate the company began its development of the CSMP in September 2007, following a meeting with the DEA, and that the program was launched the following April, in 2008.[422] Regarding the 2008 CSMP, and with respect to prospective customer due diligence, McKesson told the Committee:

> McKesson's CSMP established standardized procedures for customer diligence. For example, new pharmacy customers were required to submit a questionnaire that called for information about the pharmacy's purchase history, background, and business. The CSMP also provided for customer site visits, which could include on-site interviews. During

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[418] *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (2018) (Responses to Questions for the Record submitted by Cardinal Health, Inc.).

[419] *See Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (2018) (Responses to Questions for the Record submitted by Cardinal Health, Inc.).

[420] *See* Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).

[421] *Id.*

[422] McKesson Corp., McKesson Pharmaceutical Controlled Substance Monitoring Program (CSMP) – DEA Discussion Document, July 31, 2008, 5 (On file with Committee).

> a site visit, McKesson personnel were expected to observe, among other things, whether customer traffic appeared to be consistent with the pharmacy's business type and overall volume. Directors of Regulatory Affairs were responsible for analyzing the questionnaires and supporting documentation and making determinations about whether new customers were eligible to purchase controlled substances.[423]

Under the 2008 CSMP, and no later than January 2010, McKesson required prospective customers to provide the company with six months of dispensing data if the prospective customer estimated on the pharmacy questionnaire that its dispensing levels for certain controlled substances, including hydrocodone and oxycodone, exceeded 5,000 doses a month.[424] In an undated pharmacy questionnaire, McKesson required prospective customers to provide "information to support purchase levels" if the prospective customer estimated that its dispensing levels exceeded 5,000 doses a month.[425] This questionnaire, which likely predates January 2010, did not state what information the prospective customer was required to provide to support its estimated purchase levels, but did provide space for the prospective customer to draft a narrative explanation.[426]

McKesson told the Committee, "[i]n 2013 McKesson devoted substantial resources to enhance and revise its CSMP."[427] Documents produced to the Committee indicate that McKesson updated its pharmacy questionnaire in August 2013 and required pharmacies to provide three months of dispensing data, if requested by the company.[428] Since McKesson utilized the same pharmacy questionnaire to review its prospective and existing customers, and based on the policies and procedures produced to the Committee, it is unclear whether the production of three months of dispensing data was at the company's discretion for both prospective and existing customers or whether prospective customers were required to produce this data in all cases.

In June 2015, McKesson updated its policies, making clear that prospective customers are required to produce "[t]hree (3) months script & dose data unless the pharmacy is a Start-up

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[423] Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).
[424] *See e.g.* McKesson Corp., Pharmacy Questionnaire – Family Discount Pharmacy, Jan. 26, 2010 (On file with Committee).
[425] *See* McKesson Corp., Pharmacy Questionnaire – Family Discount Pharmacy (Stollings) (On file with Committee).
[426] *Id.*
[427] *See* Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).
[428] *See e.g.* McKesson Corp., Pharmacy Questionnaire – Hurley Drug Company, May 6, 2014 (On file with Committee); *See also* McKesson Corp., McKesson Operations Manual for Pharma Distribution – Controlled Substance Monitoring Program, 32 (Document created Feb. 11, 2008 and last revised Sept. 24, 2013) (On file with Committee).

Pharmacy or the prospective customer has been in business less than three months."[429] This dispensing data do not, however, identify a pharmacy's prescribing physicians as McKesson told the Committee, "McKesson does not require the dispensing data provided by the customer to identify prescribing physicians[,]" though noting "McKesson, may, depending on the circumstances, request that the customer provide additional information on prescribers."[430]

### *d. H.D. Smith's Approach to Prospective Customer Due Diligence*

According to H.D. Smith, in September 2007 the company's Vice-President of Corporate Compliance and Security attended a DEA industry conference addressing suspicious order monitoring.[431] Thereafter, the company stated it engaged in ongoing discussions with the DEA throughout the fall of 2007 as the company continued to develop its controlled substance order monitoring program (CSOMP), which was implemented company-wide throughout 2008.[432] With respect to prospective customer due diligence, the company told the Committee:

> Throughout 2007, the development of CSOMP was not the only enhancement made to H.D. Smith's compliance program. In December 2007, H.D. Smith implemented a more robust "know your customer" approach to customer monitoring. To that end, H.D. Smith directed its sales representatives to obtain in-person detailed Customer Profiles from all current customers. The Customer Profile form collected a variety of information to allow H.D. Smith to understand the pharmacy, its business model, the patients it services and the physicians treating those patients. Moving forward, all new customers were required to submit a completed Customer Profile for approval by [Corporate Compliance and Security Department] before they were permitted to order.[433]

Based on documents produced to the Committee, the Customer Profile form H.D. Smith utilized during 2007 and 2008 was three-pages in length and required prospective customers to provide, among other things, estimates regarding the percentage of its purchases that would be for controlled substances, as well as a narrative explanation if the pharmacy anticipated ordering a large volume of controlled substance.[434]

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[429] McKesson Corp., ISMC Controlled Substance Monitoring Program Operating Manual, 10 (Effective Date June 1, 2015 and last revised May 17, 2017) (On file with Committee).
[430] E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee).
[431] Letter from Counsel to H.D. Smith Wholesale Drug Co., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., Feb. 26, 2018 (On file with Committee).
[432] *Id.*
[433] *Id.*
[434] *See* H.D. Smith Wholesale Drug Co., Customer Profile – Family Discount Pharmacy, Dec. 18, 2007 (On file with Committee); *see also* H.D. Smith Wholesale Drug Co., Customer Profile – Hurley Drug Company, Feb. 27, 2008 (On file with Committee).

have been filed against the Company, the Company has been forced to shut its doors and go out of business."[452]

### 2. Case Studies from the Committee's Investigation

Despite these processes and procedures, documents obtained during the Committee's investigation showed, by and large, a cursory due diligence process.

The documents also showed little evidence that distributors considered, or requested additional explanation, when provided with information during the diligence process that should have raised a red flag. The Committee found instances where wholesale distributors established, or in some cases, reestablished business relationships with questionable pharmacies despite the presence of multiple red flags. Examples highlighted by the below case studies include that:

- AmerisourceBergen apparently failed to investigate why one of a prospective pharmacy's top prescribing physicians was located an approximate 11-hour roundtrip drive away;

- McKesson decided to do business with a pharmacy it knew was named in a civil lawsuit related to opioid distribution yet failed to question the pharmacy's owner about the lawsuit when it was considering the pharmacy's application in 2015. But months later, after the pharmacy became the subject of negative national media coverage, McKesson cut off the pharmacy, citing the previously-acknowledged lawsuit as the primary reason for its decision; and

- H.D. Smith seemingly failed to fully consider the company's prior engagement with a pharmacy when it agreed to onboard the pharmacy for a second time in 2015, despite the pharmacy's recent termination by two other wholesale distributors.

Most striking, however, was the overall lack of due diligence documents on many pharmacies specifically requested by the Committee. The Committee was told by one distributor that the lack of documents today does not necessarily mean that there were no documents at the time. However, that distributor also could not explain why it did not retain, or why it was unable to locate, due diligence files for one of its former customers.

[452] Letter from Counsel to Miami-Luken, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, Oct. 8, 2018 (On file with Committee).

### a. *Case Study on McKesson: Creating and Maintaining Robust Due Diligence Files*

Distributors have a legal obligation to conduct robust due diligence on their prospective and current customers. Concomitant to this obligation is the need to create and maintain complete due diligence files on an ongoing basis. Doing so better informs prospective customer evaluations and assists distributors in conducting meaningful ongoing evaluations of their existing customers.

McKesson began its business relationship with Sav-Rite Pharmacy (hereinafter "Sav-Rite No. 1") in February 2006, at the latest.[453] Sav-Rite No. 1 was located in Kermit, West Virginia, which had a population of 406 in the 2010 census.[454] According to data provided by McKesson, and as illustrated in the chart below, between February 2006 and November 2007, McKesson supplied Sav-Rite No. 1 with more than 5.66 million doses of hydrocodone and oxycodone.[455] The volume of drugs sent to the pharmacy during that two-year period alone made it McKesson's third highest overall hydrocodone and oxycodone purchaser in West Virginia between 2006 and 2017.[456]

| **McKesson Distribution to Sav-Rite No. 1**[457] | |
|---|---|
| **2006** | |
| **Drug** | **Dosage Units** |
| Hydrocodone | 2,477,841 |
| Oxycodone | 78,500 |
| **2007** | |
| Hydrocodone | 3,068,805 |
| Oxycodone | 40,960 |
| **Total** | **5,666,106** |

**FINDING: McKesson supplied Sav-Rite No. 1 pharmacy with more than 5.66 million doses of hydrocodone and oxycodone in 2006 and 2007. Based on these two years alone, Sav-Rite No. 1 was McKesson's third largest hydrocodone and oxycodone purchaser in West Virginia between 2006 and 2017.**

Despite this volume, McKesson was only able to produce a single due diligence document to the Committee related to this pharmacy—a November 2007 written declaration from Sav-Rite No. 1's owner—representing that the pharmacy fills only legitimate

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[453] *See* Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee). In its letter to the Committee, McKesson stated that February 2006 was the most recent sales data that was available to the company and that McKesson assumed Sav-Rite No. 1 as a customer after McKesson acquired D&K Healthcare Resources, a regional wholesale distributor, in late 2005.
[454] American FactFinder, *Kermit (town), West Virginia* (https://factfinder.census.gov).
[455] McKesson Corp., 2006 – 2017 Sales Data (On file with Committee).
[456] *Id.*
[457] *Id.*

prescriptions.[458] The November 2007 written declaration from Sav-Rite No. 1's owner is reproduced in its entirety below:

[458] James P. Wooley, Declaration of Controlled Substances, Nov. 1, 2007 (On file with Committee). McKesson also produced to the Committee a May 2007 e-mail that mentions Sav-Rite No. 1 as well as Family Discount Pharmacy. *See* E-Mail from Staff, McKesson Corp., to Staff, McKesson Corp. (May 9, 2007 4:14 pm) (On file with Committee). This e-mail was not produced in satisfaction of the Committee's February 15, 2018 request that McKesson provide all documents related to McKesson's due diligence file for Sav-Rite No. 1. *See* Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to John H. Hammergren, Chairman, President and Chief Exec. Officer, McKesson Corp., Feb. 15, 2018. Rather, McKesson's production of the May 2007 e-mail was in response to a supplemental question posed by the Committee on July 31, 2018 regarding a representation McKesson made to the Committee on June 11, 2018. *See* E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee).

[redacted]

**DECLARATION OF**
**CONTROLLED SUBSTANCES PURCHASES**

1. Sav-Rite Pharmacy dba Sav-Rite Pharmacy [pharmacy name] (hereinafter "Pharmacy") located at US HWY 52 Kermit, WV [address, city and state] is registered with the Drug Enforcement Administration (DEA), [redacted] [DEA registration #].

2. Pharmacy declares and attests that it fully complies with all federal and state laws and regulations on the dispensing of controlled substances including but not limited to dispensing to patients only pursuant to a legitimate prescription issued in the course of an established doctor-patient relationship (e.g., pursuant to a physical examination) and only for a legitimate medical purpose.

3. Pharmacy will not knowingly dispense controlled substances for prescriptions that have been received via the internet, mail-order, or other non-walk-in customer where it has reason to believe that the prescription was issued without a legitimate medical purpose.

4. Pharmacy states that its requirements for purchases of Lifestyle Drugs (e.g., hydrocodone, phentermine, alprazolam, oxycodone) from McKesson are necessary for the following reasons: *[please describe the reason for purchasing these drugs in the quantities requested including information about the prescriber and the general purposes for which the drugs are being prescribed.)*

Sav-Rite Pharmacy fills only controlled drugs from legitimate physicians (licensed) for the patients that the pharmacy has a patient/Pharmacy relationship - We do not do computer-internet prescription filling -

Jim Worley, Pharmacist
Sav-Rite Pharmacy

5. Pharmacy certifies that it has made sufficient inquiry to be able to make this declaration truthfully, accurately and without material omissions. Pharmacy affirms by signing this declaration that the above is true and correct to the best of its knowledge and belief.

[redacted]

James P. Wooley

Printed Name of Signer

Pharmacist - Owner 11-1-07

**FINDING: McKesson's due diligence file for Sav-Rite No. 1 contained only one document, a November 2007 written declaration from the pharmacy's owner representing that the pharmacy sells only legitimate prescriptions.**

At the Subcommittee's May 8, 2018 hearing, McKesson President, CEO, and Board Chairman, John Hammergren was unable to say whether McKesson had any due diligence documentation beyond this written declaration with respect to the company's engagement with Sav-Rite No. 1:

> Q. Now, in your written testimony, Mr. Hammergren, you put a lot of thought into using population statistics and other arguments to justify your shipments to Sav-Rite and other pharmacies. We just heard Mr. Barrett talking about that, too. But when the committee asked you to provide McKesson's due diligence file for Sav-Rite,

you gave us a single document from 2007. Do you recognize this document, sir?

A. No, I don't.

Q. Okay. It's exhibit 3 in the binder. Do you recognize that document now? You don't.

A. This is the first time I've seen this document.

Q. Okay. Well, I will tell you for the record that this document, which says declaration of controlled substances purchases, which is a two-page document, is the only documentation that McKesson gave to this committee when we asked for the due diligence file for Sav-Rite. Do you think this fulfills the requirements of the DEA that your company do due diligence for distribution of opioids to this city?

A. I believe our relationship with Sav-Rite should have been terminated immediately.

Q. Yes or no, do you think this is sufficient documentation to show compliance with the rules of the DEA?

A. We continue to evolve our diligence - -

Q. Yes or no will work, sir.

A. I've not reviewed the document. I can't provide an answer to that.[459]

McKesson told the Committee that it assumed Sav-Rite No. 1 as a customer following McKesson's acquisition of D&K Healthcare Resources in late 2005.[460] The Committee asked McKesson whether it performed new customer due diligence for the pharmacies that it assumed through this acquisition, including Sav-Rite No. 1.[461] In response, McKesson told the

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[459] *See Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. 58 – 59(2018) (testimony of John H. Hammergren, Chairman, President, and CEO, McKesson Corp.) *available at* https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Transcript-20180508.pdf.

[460] *See* Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).

[461] Briefing, Staff, McKesson Corp., to Staff, H. Comm. on Energy and Commerce, May 4, 2018 and E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to McKesson Corp. (July 31, 2018 11:10 am) (On file with Committee).

Committee, "[o]ur present understanding is that at the time of the acquisition specific customer evaluations were not performed."[462]

When McKesson acquired Sav-Rite No. 1 as a customer and for nearly two years thereafter, the lack of documents produced to the Committee suggest it failed to conduct and document necessary new or existing customer due diligence on the pharmacy. Had McKesson done so, the company presumably would have been made aware of potential red flags associated with the pharmacy, allowing the company to terminate the pharmacy in a timelier manner, possibly preventing millions of doses of opioids from being sent to a pharmacy that was engaged in diversion.

### b. *Case Study on McKesson: Reengaging with a Customer After Termination*

The need to maintain complete, robust due diligence files is also demonstrated in situations where a distributor may receive a new customer application from a pharmacy that it had a business relationship with previously, or from a pharmacy that a distributor considered in the past but ultimately denied the pharmacy's application. Maintaining and consulting such due diligence files allows distributors to be more attuned to any possible red flags associated with a pharmacy as well as any potential discrepancies that may exist on the pending new customer application. However, it appears that McKesson did not always follow those practices.

#### i. *McKesson's Initial Engagement with Family Discount Pharmacy*

Family Discount Pharmacy in Mount Gay-Shamrock, West Virginia, was McKesson's biggest purchaser of hydrocodone and oxycodone in West Virginia between 2006 and 2017.[463] McKesson supplied Family Discount Pharmacy with more than 5.91 million doses of hydrocodone and oxycodone during six years between 2006 and 2014.[464] Between 2006 and 2007 alone, McKesson provided Family Discount Pharmacy with more than 3.82 million doses of hydrocodone.[465] As will be described below, McKesson terminated this pharmacy prior to 2008 for "compliance reasons" but elected to onboard the customer again two times thereafter.

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[462] E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee).
[463] McKesson Corp., 2006 – 2017 Sales Data (On file with Committee).
[464] *Id.*
[465] *Id.*

| McKesson Distribution to Family Discount Pharmacy[466] | |
|---|---|
| **2006** | |
| **Drug** | **Dosage Units** |
| Hydrocodone | 1,846,850 |
| Oxycodone | 96,680 |
| **2007** | |
| Hydrocodone | 1,753,732 |
| Oxycodone | 126,070 |
| **2008** | |
| Hydrocodone | 0 |
| Oxycodone | 0 |
| **2009** | |
| Hydrocodone | 0 |
| Oxycodone | 0 |
| **2010** | |
| Hydrocodone | 81,900 |
| Oxycodone | 8,690 |
| **2011** | |
| Hydrocodone | 0 |
| Oxycodone | 0 |
| **2012** | |
| Hydrocodone | 382,260 |
| Oxycodone | 57,320 |
| **2013** | |
| Hydrocodone | 987,831 |
| Oxycodone | 297,930 |
| **2014** | |
| Hydrocodone | 175,758 |
| Oxycodone | 104,600 |
| **Total** | **5,919,621** |

**FINDING: Family Discount Pharmacy in Mount Gay-Shamrock was McKesson's biggest purchaser of hydrocodone and oxycodone in West Virginia between 2006 and 2017. McKesson supplied the pharmacy with more than 5.91 million doses of hydrocodone and oxycodone during six years between 2006 and 2014, including more than 3.82 million doses in between 2006 and 2007 alone.**

Among other information related to McKesson's relationship with Family Discount Pharmacy, the Committee requested that McKesson provide "all documents related to

[466] *Id.*

McKesson's due diligence files for Family Discount Pharmacy of Mount Gay-Shamrock."[467] Aside from a single e-mail sent in May 2007, and produced in response to a supplemental question the Committee posed regarding Sav-Rite No. 1,[468] the earliest document McKesson produced to the Committee for Family Discount Pharmacy of Mount Gay-Shamrock was from January 2010. Notably, apart from the May 2007 e-mail, which is reproduced below, McKesson did not produce any due diligence documents from 2006 or 2007, in which it supplied this pharmacy with more than 3.82 million doses of hydrocodone, or earlier than 2006.

**From:** [redacted] [/O=MCKESSON/OU=NORTH AMERICA/CN=RECIPIENTS/CN=743A9CA9]
**Sent:** 5/9/2007 11:34:59 PM
**To:** [redacted]
**Subject:** FW: Daily Dosage

Today I sat down and went through DC by DC. These two along with Garden in Lakeland really stick out. You and can connect by phone later this week or early next week, I have some thoughts on analysis.

[redacted]

**From:** [redacted]
**Sent:** Wednesday, May 09, 2007 4:14 PM
**To:** [redacted] (Washington Court House)
**Cc:** [redacted]
**Subject:** Daily Dosage

[redacted] I have been going through the April Daily Dosage for all DC's. Two of your customers really jumped out at me

Family Discount Phcy
Sav-Rite Phcy

We need to document those ASAP and I would like to understand their business that would drive the numbers

[redacted]

This e-mail is the only document the Committee received from McKesson that may relate to its apparent termination of the pharmacy, which, based on the data, appears to have occurred in 2007.[469] As seen in the chart above, McKesson did not supply any opioids to Family Discount Pharmacy in Mount Gay-Shamrock in 2008 and 2009. When asked about the cessation of distribution in these years, McKesson told the Committee that it "believes" it terminated the customer "for compliance reasons." Specifically, McKesson told the Committee:

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[467] *See* Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to John H. Hammergren, Chairman, President and Chief Exec. Officer, McKesson Corp., Feb. 15, 2018 *available at* https://energycommerce.house.gov/wp-content/uploads/2018/02/20180215McKesson.pdf.

[468] *See* E-Mail from Staff, McKesson Corp., to Staff, McKesson Corp. (May 9, 2007 11:34 pm) (On file with Committee); *See also* E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee). This e-mail was not produced in satisfaction of the Committee's February 15, 2018 request that McKesson provide all documents related to McKesson's due diligence file for Family Discount Pharmacy.

[469] McKesson did not produce any documents to the Committee that included the date that Family Discount Pharmacy in Mount Gay-Shamrock was terminated as a customer. The Committee infers from the data that this occurred in 2007, given that no distribution occurred in 2008. The Committee cannot determine from the data and documents the date on which this customer was terminated in 2007.

> McKesson did not sell the Family Discount Pharmacy in Mount Gay any oxycodone or hydrocodone products in 2008, 2009 and 2011 and, compared to other years, a significantly smaller quantity of those products in 2010. McKesson has conducted a diligent search of its records and has not located a due diligence file for 2008 and 2009. In an e-mail to DEA on February 6, 2009, McKesson provided the agency with a list of pharmacies that had been terminated for compliance reasons. McKesson included Family Discount Pharmacy in Mount Gay on this list. Based on this e-mail, McKesson believes that the lack of sales in 2008 and 2009 can be attributed to a decision to terminate Family Discount Pharmacy in Mount Gay as a customer.[470]

The February 2009 e-mail to the DEA was not produced to the Committee as part of the due diligence file for Family Discount Pharmacy, indicating that it was not included with McKesson's due diligence materials for this pharmacy. In fact, aside from that e-mail, the due diligence file did not contain a single document related to the apparent termination of this customer.

| | |
|---|---|
| **FINDING:** | **McKesson did not retain sufficient due diligence files documenting its relationship with Family Discount Pharmacy in Mount Gay-Shamrock during 2006 and 2007, including documentation regarding the company's apparent decision to terminate the pharmacy as a customer for "compliance reasons."** |

### *ii. McKesson's Second Engagement with Family Discount Pharmacy*

Notwithstanding the decision to terminate the pharmacy "for compliance reasons," McKesson reinstated Family Discount Pharmacy as a customer in 2010 and supplied the pharmacy with controlled substances.[471] The due diligence materials produced to the Committee to support this decision included a six-page new customer questionnaire and dispensing information for the pharmacy. In the questionnaire component of McKesson's new customer due diligence in January 2010, Family Discount Pharmacy represented that its ability to purchase controlled substances had never been terminated or restricted by a distributor in the past.[472] The portion of the 2010 questionnaire where Family Discount Pharmacy made this representation is reproduced below:

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[470] Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).
[471] McKesson Corp., 2006 – 2017 Sales Data (On file with Committee).
[472] McKesson Corp., Pharmacy Questionnaire – Family Discount Pharmacy, Jan. 26, 2010 (On file with Committee).

vii. **Has any previous wholesaler ceased shipping or restricted purchases of controlled substances?**

☐ Yes ☑ No

That representation, however, seems directly contradicted by McKesson's claim that it terminated Family Discount as a customer "for compliance reasons," likely in 2007. The documents produced to the Committee give no indication to suggest that McKesson made any further inquiry to resolve this discrepancy or otherwise considered its prior termination "for compliance reasons" when reinstating Family Discount as a customer in 2010.

The Committee asked McKesson whether it addressed this contradiction when it was considering Family Discount's application in 2010.[473] In response, McKesson told the Committee "[b]ased on the available due diligence files, McKesson conducted an onboarding review of the customer, which included having the customer submit a questionnaire. At this time, McKesson has not located additional information to explain this issue[.]"[474]

In its response to the Committee's question, McKesson did provide an e-mail chain among McKesson personnel during the time it was considering Family Discount's application in 2010, which, according to McKesson, "provides some additional context."[475] The e-mail chain produced by McKesson makes no mention of the company's previous engagement with Family Discount and its decision to terminate the pharmacy "for compliance reasons." In one e-mail, for example, a member of McKesson's regulatory affairs division stated, "I cannot see any reason we should be hesitant even with the large numbers he is talking about."[476] This e-mail is reproduced below:

**From:** [redacted]
**Sent:** Wednesday, January 27, 2010 2:47 PM
**To:** [redacted]
**Cc:** [redacted]; [redacted]
**Subject:** RE: Family Pharmacy

Guys
I have done some internet research and find no mention of the pharmacy or the pharmacist except good stories of community assistance, etc. I cannot see any reason we should be hesitant even with the large numbers he is talking about. (155k hydro and 110k alpraz, etc)
You are welcome, [redacted] Thank you all too.
[redacted] DRA North Central

[473] *See* E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to McKesson Corp. (July 31, 2018 11:10 am) (On file with Committee).
[474] E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee).
[475] *Id.*
[476] E-Mail from Staff, McKesson Corp., to Staff, McKesson Corp. (Jan. 27, 2010 2:47 pm) (On file with Committee).

**FINDING: McKesson did not consider its prior relationship with Family Discount Pharmacy when evaluating the pharmacy's new customer application in 2010, with a member of McKesson's regulatory affairs division at one point stating, "I cannot see any reason we should be hesitant" with respect to the pharmacy.**

The e-mails provided by McKesson suggest that the company viewed itself as being in competition with other distributors to obtain Family Discount's account. For example, in an e-mail to a McKesson Vice President and General Manager referencing a pricing proposal for Family Discount Pharmacy, a member of McKesson's sales division noted the pharmacy had a "very aggressive buy plan with Cardinal. I would approve this based on where we have to be to have an opportunity."[477] The e-mail is reproduced below:

**From:** [redacted]
**Sent:** Monday, February 01, 2010 11:37 AM
**To:** [redacted]
**Cc:** [redacted]
**Subject:** FW: Family Pharmacy - EPIC

[redacted]
Please see attached. He currently has a very aggressive buy plan with Cardinal. I would approve this based on where we have to be to have an opportunity.

Thanks
[redacted]

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**From:** [redacted]
**Sent:** Monday, February 01, 2010 12:14 PM
**To:** [redacted]
**Subject:** FW: Family Pharmacy - EPIC

[redacted]
I would like to request approval to offer the pricing in the attachment to Family Discount – Mt Gay.
The offering is for cost -3.40% on 700K per month, EPIC with a 2.90% ebit.
Please advice.
Thanks,

[redacted]
McKesson WCH

In another e-mail, a member of McKesson's sales division said that he was sure either H.D. Smith or Cardinal Health would offer to be Family Discount's secondary distributor if McKesson were to "win" Family Discount's business.[478]

In the January 2010 questionnaire, and referenced above, Family Discount Pharmacy estimated that it dispensed an average of 155,000 doses of hydrocodone a month, which equals 1.86 million doses a year. The pharmacy also estimated that it dispensed an average of 110,000

[477] E-Mail Staff, McKesson Corp., to Staff, McKesson Corp. (Feb. 1, 2010 11:37 am) (On file with Committee).
[478] E-Mail Staff, McKesson Corp., to Staff, McKesson Corp. (Jan. 27, 2010 4:39 pm) (On file with Committee).

doses of alprazolam a month, which equals 1.32 million doses a year.[479] For reference, according to U.S. Census data, Mount Gay-Shamrock, West Virginia had a population of 1,779 in 2010.[480] On its new customer questionnaire, McKesson required pharmacies provide six months of dispensing data if estimated dispensing data exceeded 5,000 doses a month for certain controlled substances, including hydrocodone and alprazolam.[481] The due diligence documents provided to the Committee do not give any indication that McKesson analyzed the dispensing data that Family Discount Pharmacy provided.

According to documents produced to the Committee, McKesson onboarded Family Discount and set the pharmacy's hydrocodone ordering threshold at 155,000 dosage units a month—a level 31 times more than what McKesson determined warranted supplementary documentation on its new customer questionnaire.[482]

One day after Family Discount submitted its new customer questionnaire, a McKesson sales representative sent an e-mail to McKesson staff, saying, "[j]ust talked to [redacted] he said that those thresholds sound good."[483] The e-mail from the McKesson sales representative is reproduced below:

**From:** [redacted]
**Sent:** Wednesday, January 27, 2010 4:39 PM
**To:** [redacted] [redacted]
**Cc:** [redacted]
**Subject:** RE: Family Pharmacy

Thanks [redacted] I appreciate the time you took on this prospect. Just talked to [redacted] he said that those thresholds sound good.

**FINDING: In 2010, McKesson set the hydrocodone threshold for Family Discount Pharmacy, a pharmacy previously terminated by McKesson for compliance reasons, at a level that was 31 times higher than what the company determined warranted supplementary explanation on its new customer questionnaire.**

In 2010, McKesson's relationship with Family Discount Pharmacy only lasted a little over three weeks. McKesson told the Committee:

> McKesson records indicate that Family Discount Pharmacy (Mount Gay-Shamrock)'s first controlled substances order in 2010 was on March 2, and its last controlled substances order in 2010 was on March 26. Currently

[479] McKesson Corp., Pharmacy Questionnaire – Family Discount Pharmacy, Jan. 26, 2010 (On file with Committee).
[480] American FactFinder, *Mount Gay-Shamrock CDP, West Virginia* (https://factfinder.census.gov).
[481] McKesson Corp., Pharmacy Questionnaire – Family Discount Pharmacy, Jan. 26, 2010 (On file with Committee).
[482] McKesson Corp., Hydrocodone thresholds – Family Discount Pharmacy, Mount Gay-Shamrock, (On file with Committee).
[483] E-Mail Staff, McKesson Corp., to Staff, McKesson Corp. (Jan. 27, 2010 4:39 pm) (On file with Committee).

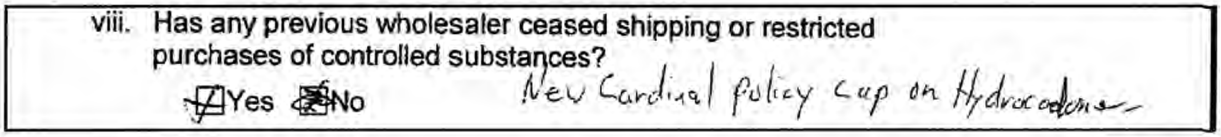
available records do not make clear why McKesson discontinued supplying controlled substances to the pharmacy in 2010.[484]

In the brief time it supplied the pharmacy with controlled substances in March 2010, McKesson supplied Family Discount Pharmacy with more than 90,000 doses of hydrocodone and oxycodone.[485] As indicated, however, McKesson did not provide the Committee with any documents that would indicate why its relationship with the pharmacy was discontinued after March 26, 2010.

### *iii. McKesson's Third Engagement with Family Discount Pharmacy*

McKesson resumed a business relationship with Family Discount Pharmacy in Mount Gay-Shamrock in September 2012, when McKesson agreed to onboard the pharmacy as a customer for a third time.[486] The 2012 due diligence file on Family Discount Pharmacy that was produced to the Committee included a seven-page new customer questionnaire, a six-month dispensing report, photos of the pharmacy, and e-mails to pharmaceutical manufacturers seeking additional information on the pharmacy. The due diligence file also included internal McKesson e-mails which indicate that McKesson evaluated the pharmacy's prescribing physicians and performed a site visit to the pharmacy, though the due diligence file did not include McKesson's analysis of the prescribing physicians or a report of the site visit. McKesson also contacted the West Virginia Board of Pharmacy, which reported that the pharmacy was "a reliable high volume account" and noted that the pharmacy "may have had an issue a long time ago, but according to the West Virginia Board of Pharmacy that issue had been resolved and was a reliable pharmacy."[487]

In the questionnaire component of McKesson's new customer due diligence process, and as indicated below, the pharmacy disclosed that its ability to purchase controlled substances had been restricted or terminated in the past, citing a "new Cardinal policy cap on Hydrocodone."[488]


viii. Has any previous wholesaler ceased shipping or restricted purchases of controlled substances?
☑ Yes ☒ No New Cardinal policy cap on Hydrocodone

The pharmacy did not disclose, however, that McKesson had also previously terminated its ability to purchase controlled substances, as discussed earlier. Nor does McKesson appear to

[484] E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 12, 2018 4:22 pm) (On file with Committee).
[485] McKesson Corp., 2006 – 2017 Sales Data (On file with Committee).
[486] McKesson Corp., Pharmacy Questionnaire – Family Discount Pharmacy, Aug. 24, 2012 (On file with Committee).
[487] Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee).
[488] McKesson Corp., Pharmacy Questionnaire – Family Discount Pharmacy, Aug. 24, 2012 (On file with Committee).

have examined its own two prior engagements with the pharmacy. In the documents that were produced to the Committee, the only mention of the pharmacy's history with McKesson appears to be in an e-mail from a member of McKesson's sales staff, sent days after receiving the pharmacy's 2012 application, noting "[t]his account had been previous [sic] approved to purchase CSMP items from us, but has since switched to Cardinal. We have a chance to get them back pending your approvals."[489] This e-mail is reproduced below:

**From:** [redacted]/O=MCKESSON/OU=NORTH AMERICA/CN=RECIPIENTS/CN=TK7JBSW]
**Sent:** 8/28/2012 7:20:59 PM
**To:** [redacted]
**CC:** [redacted]
**Subject:** propective customer CSMP Questionnaire Family Discount Pharmacy

Please see attached CSMP Questionnaire 6 month usage report and facility photos for a prospect (Family Discount Pharmacy) [redacted] and I have been working on. This account had been previous approved to purchase CSMP items from us, but has since switched to Cardinal. We have a chance to get them back pending your approvals.

In addition to the attached 6 month usage report I have an additional report that shows usage by prescription and physician who wrote prescription. This report is rather large and will have to be Fed Ex to [redacted] [redacted] you should receive tomorrow or no later than Thursday. Once you receive and review please call to discuss.

Thanks,

[redacted]

Moreover, based upon the documents reviewed by the Committee, McKesson does not appear to have asked the pharmacy for any additional information regarding why Cardinal restricted purchases of controlled substances. Rather, e-mails produced to the Committee suggest that McKesson was concerned that other distributors, and potentially Cardinal, would acquire Family Discount's business if McKesson did not act fast enough. For example, in an e-mail to a member of McKesson's regulatory affairs division, a McKesson distribution center manager stated, "[t]he customer is ready to make the change, and if we put [a site visit] off that will give our competitors time to come back in and try to keep it."[490] The e-mail also noted that McKesson was evaluating some of the physicians that had been provided by the pharmacy. This e-mail is reproduced below:

[489] E-Mail Staff, McKesson Corp., to Staff, McKesson Corp. (Aug. 28, 2012 7:20 pm) (On file with Committee).
[490] E-Mail Staff, McKesson Corp., to Staff, McKesson Corp. (Sept. 5, 2012 8:52 pm) (On file with Committee).

**From:** [redacted]
**Sent:** Wednesday, September 05, 2012 8:52 PM
**To:** [redacted]
**Cc:** [redacted] [redacted]
**Subject:** Family Discount

[redacted]

I spoke with [redacted] and [redacted] about this account and they want to know if there is any way at all you can visit this account this week. The customer is ready to make the change, and if we put it off that will give our competitors time to come back in and try to keep it. Can you make the visit? I will have [redacted] check on some of the doctors they gave us. If there is anything else that you want me to do let me know and [redacted] or I will work on it, but they really want to get moving on this one way or the other.

Thanks
[redacted]

In a separate e-mail a member of McKesson's sales division characterized the pharmacy as a "real opportunity" and requested that the scheduling of the site visit be expedited.[491] This e-mail is reproduced below:

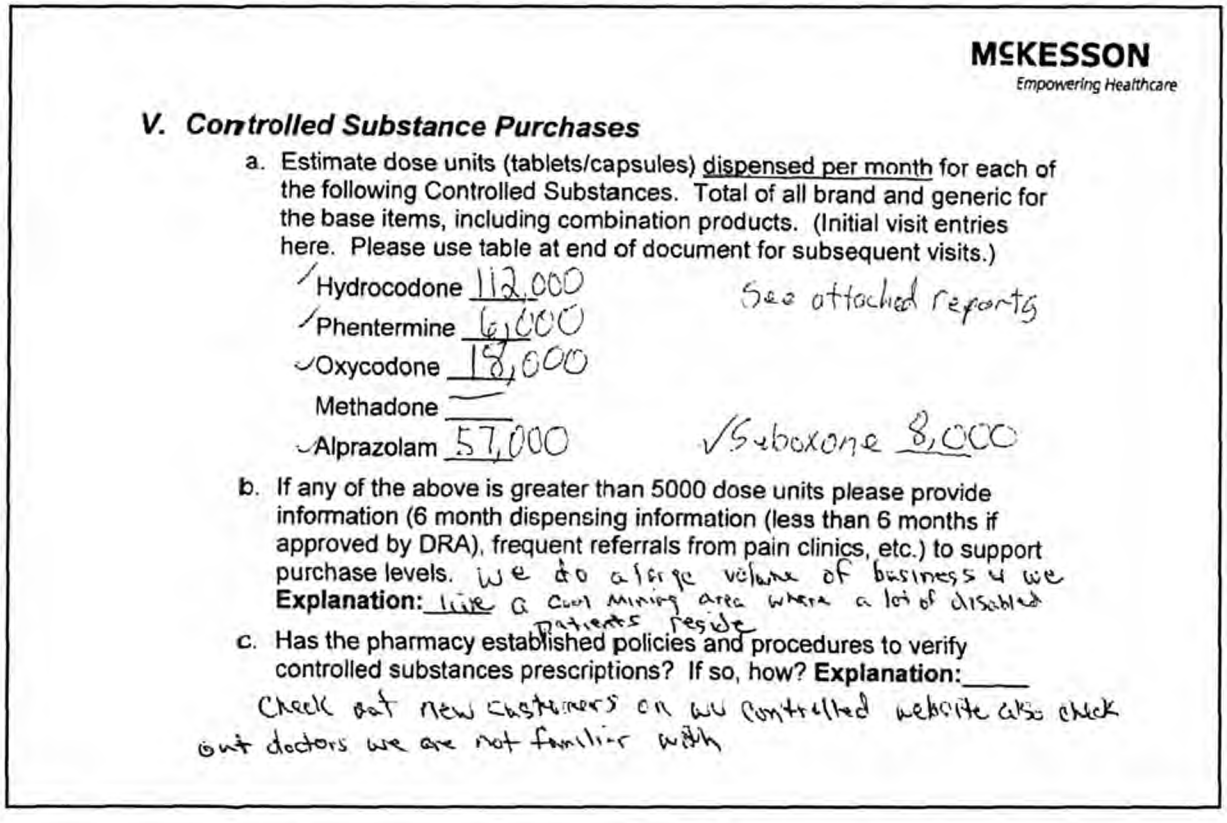
**From:** [redacted]
**Sent:** Tuesday, September 04, 2012 10:18 PM
**To:** [redacted]; [redacted]; [redacted]
**Cc:** [redacted]
**Subject:** RE: Prospect Family Discount Pharmacy

Real opportunity here. Please expedite and thanks

In the 2012 new customer questionnaire, Family Discount Pharmacy estimated that it dispensed 112,000 dosage units of hydrocodone per month, on average, which equals more than 1.34 million doses per year.[492] On its questionnaire, McKesson required pharmacies to provide six months of dispensing data if they estimated dispensing more than 5,000 dosage units a month of certain controlled substances, including hydrocodone. In addition to providing the dispensing data, and to justify its dispensing levels, which were more than 22 times the amount necessary to trigger a supplemental examination, the pharmacy explained, "[w]e do a large volume of business [and] we live [in] a coal mining area where a lot of disabled patients reside."[493] The

[491] E-Mail Staff, McKesson Corp., to Staff, McKesson Corp. (Sept. 4, 2012 10:18 pm) (On file with Committee).
[492] McKesson Corp., Pharmacy Questionnaire – Family Discount Pharmacy, Aug. 24, 2012 (On file with Committee).
[493] *Id.*

portion of the 2012 new customer questionnaire where Family Discount provided its estimated dispensing data and supplemental explanation is reproduced below:



McKESSON
Empowering Healthcare

**V. Controlled Substance Purchases**

a. Estimate dose units (tablets/capsules) dispensed per month for each of the following Controlled Substances. Total of all brand and generic for the base items, including combination products. (Initial visit entries here. Please use table at end of document for subsequent visits.)

Hydrocodone 112,000
Phentermine 6,000
Oxycodone 18,000
Methadone —
Alprazolam 57,000

See attached reports

Suboxone 8,000

b. If any of the above is greater than 5000 dose units please provide information (6 month dispensing information (less than 6 months if approved by DRA), frequent referrals from pain clinics, etc.) to support purchase levels. **Explanation:** we do a large volume of business u we live a coal mining area where a lot of disabled Patients reside

c. Has the pharmacy established policies and procedures to verify controlled substances prescriptions? If so, how? **Explanation:**

Check out new customers on ww controlled website also check out doctors we are not familiar with

Documents produced to the Committee indicate McKesson onboarded Family Discount after less than one month of review in September 2012 and set the pharmacy's hydrocodone ordering threshold at 112,000 dosage units a month.[494] McKesson told the Committee:

> In October 2012, Family Discount Pharmacy (Mount Gay-Shamrock)'s first full month of ordering through McKesson, it ranked first among McKesson's retail customers for controlled substance ordering in West Virginia and among customers with Washington Courthouse as their home distribution center, and nineteenth nationally. The pharmacy was a large account overall. It ranked third for *non*-controlled substance ordering among McKesson's West Virginia retail customers in October 2012, and first in controlled and non-controlled ordering combined among McKesson's West Virginia retail customers that month[495]

[494] McKesson Corp., Hydrocodone thresholds – Family Discount Pharmacy, Mount Gay-Shamrock, (On file with Committee).
[495] E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 12, 2018 4:22 pm) (Emphasis in original) (On file with Committee).

In April 2014, McKesson prohibited the pharmacy from ordering controlled substances after the company "determined that Family Discount Pharmacy was also filling prescriptions from physicians who had been identified by another McKesson customer as potentially having questionable prescribing patterns."[496]

As noted above, during McKesson's three engagements with Family Discount Pharmacy, it supplied more than 5.91 million doses of hydrocodone and oxycodone, making the pharmacy McKesson's biggest customer in West Virginia between 2006 and 2017. Had McKesson maintained robust due diligence files for Family Discount Pharmacy and consulted these files when it was considering the pharmacy's applications in 2010 and 2012, it would have been aware that it terminated the pharmacy for compliance reasons on at least one prior occasion. In addition, conducting a retrospective review of the due diligence files would have also alerted McKesson to the pharmacy's failure to disclose its previous termination by McKesson on its 2010 and 2012 new customer applications, with the pharmacy seemingly providing the company with a misrepresentation on its 2010 application in particular. Such information may have prompted McKesson to deny Family Discount's applications on multiple occasions. Instead, McKesson accepted Family Discount as a customer a total of at least three times, only to ultimately restrict its ability to purchase controlled substances again in 2014.

[496] Letter from Counsel to McKesson Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, Apr. 24, 2018 (On file with Committee). *See also* McKesson Corp., Regulatory Investigative Report – Family Discount Pharmacy (Mount Gay-Shamrock), May 2, 2014 (On file with Committee).

### c. *Case Study on McKesson: Following up on Red Flags Identified During the Due Diligence Process*

During the prospective customer due diligence process, distributors may come across potential red flags of diversion that warrant additional analysis or explanation. This information may be disclosed to distributors in a prospective customer questionnaire, through the production of a pharmacy's dispensing data, or through a distributor's independent efforts such as performing internet searches of the pharmacy and its prescribing physicians. When a distributor does identify potential red flags, it should seek further explanation from the pharmacy in addition to performing its own analysis, documenting both.

As has been documented by the Committee's investigation, Tug Valley Pharmacy and Hurley Drug Company, both located in Williamson, West Virginia, a town with a population of roughly 3,000 people, received more than 20.8 million dosages of hydrocodone and oxycodone over an eleven-year period.[497] McKesson was one of multiple distributors that supplied the town of Williamson. At the time it began supplying Williamson with opioids, the endemic nature of the town's and its surrounding area's prescription drug abuse problem had been publicly reported, along with the town's moniker of "Pilliamson."[498] According to McKesson's policies, if "[t]he pharmacy [is] located in a geographic area known or suspected of having higher than normal prescription drug diversion or level of prescribing[,]" that is a "Non-Statistical Red Flag" and a potential cause for concern.[499]

#### i. *McKesson's Initial Engagement with Tug Valley Pharmacy*

On May 12, 2015, Tug Valley Pharmacy submitted a new customer questionnaire to McKesson.[500] In this questionnaire, Tug Valley represented that another wholesale distributor had previously taken action to discontinue or restrict its ability to purchase controlled substances, noting "Miami Luken ceased all sales non-controlled and controls recently."[501] McKesson policies, with respect to the pharmacy customer questionnaire, include the example of "red flag" for diversion as a scenario wherein "[a] previous wholesaler or manufacturer ceased selling controlled substances to the pharmacy within past five years[,]."[502] The relevant portions of the questionnaire are reproduced below:

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[497] *See* Gabe Gutierrez, et. al, *Welcome to Williamson, W.Va., where there are 6,500 opioid pills per person*, NBC NEWS, Feb. 1, 2018, https://www.nbcnews.com/news/us-news/welcome-williamson-w-va-where-there-are-6-500-opioid-n843821. Documents indicate that McKesson supplied both Williamson pharmacies with opioids, beginning with Hurley Drug Company in 2014 and then Tug Valley Pharmacy the following year, 2015. *See* U.S. Drug Enforcement Admin., ARCOS Data (On file with Committee).

[498] *See* Alison Knezevich, *Prescription drug abuse plagues small W. Va. town*, CHARLESTON GAZETTE, Jan. 22, 2011 (On file with Committee); *see also* Evelyn Nieves, *Prescription pill epidemic has spiraled out of control*, SALON, Apr. 8, 2013, https://www.salon.com/2013/04/08/prescription_pill_epidemic_has_spiraled_out_of_control_partner/; Fox News, *Fatally shot West Virginia county sheriff Eugene Crum took aim at drug dealers*, FOX NEWS, Apr. 4, 2013, https://www.foxnews.com/us/fatally-shot-west-virginia-county-sheriff-eugene-crum-took-aim-at-drug-dealers.

[499] McKesson Corp., McKesson CSMP "Red Flags," May 2015 (On file with Committee).

[500] McKesson Corp., Pharmacy Questionnaire – Tug Valley Pharmacy, May 12, 2015 (On file with Committee).

[501] *Id.*

[502] McKesson Corp., McKesson CSMP "Red Flags," May 2015 (On file with Committee).

ix. Has any previous wholesaler / manufacturer ceased shipping or restricted purchases of controlled substances to this pharmacy in the past 5 years?

☒ Yes ☐ No

Explanation: Miami Luken - ceased All sales non-controlled and controls recently.

x. Has any previous wholesaler / manufacturer ceased shipping or restricted purchases of controlled substances to a pharmacy that was owned or is owned by current owner/s during the past ten years?

☒ Yes ☐ No

Explanation: Miami Luken ceased All med sales - control + non controlled

Upon receiving the questionnaire, and as documented by the due diligence files produced to the Committee, McKesson conducted supplemental due diligence, including verifying the pharmacy's and staff's state and DEA registrations as well as checking for any past disciplinary actions.[503] McKesson also reviewed the pharmacy's dispensing data for the previous three months.[504]

Less than a week after receiving Tug Valley's new customer application, a McKesson Regulatory Affairs Manager authored a due diligence report referencing Tug Valley's disclosure that Miami-Luken recently discontinued selling the pharmacy controlled and non-controlled substances, as well as pending litigation involving the pharmacy.[505] The report stated:

> Derogatory information on Tug Valley Pharmacy, LLC and pharmacist/owner [redacted] was found during a search of Internet

[503] McKesson Corp., Due Diligence Report – Tug Valley Pharmacy, May 18, 2015 (On file with Committee).
[504] McKesson Corp., Regulatory Investigative Report – Tug Valley Pharmacy, July 23, 2015 (On file with Committee). *See also* McKesson Corp., Tug Valley Pharmacy – Dispensing Data (Feb. 13, 2015 – May 13, 2015) (On file with Committee).
[505] McKesson Corp., Due Diligence Report – Tug Valley Pharmacy, May 18, 2015 (On file with Committee).

websites. Tug Valley Pharmacy, LLC and [redacted] are mentioned in a civil action (no. 10-c-251) and a circuit court order (no. 14-0144).[506]

The litigation referenced in the due diligence report involved a number of civil actions alleging that a number of West Virginia pharmacies and doctors, including Tug Valley, negligently and/or recklessly provided the plaintiffs prescriptions for controlled substances.[507] The diligence report also provided hyperlinks to court documents associated with the litigation, which were also included in the due diligence documents that were produced to the Committee. Thus, McKesson managers had knowledge of a lawsuit involving allegations related to Tug Valley's dispensing of controlled substances only days after receiving the pharmacy's new customer application.

The court documents linked in this report provide more context regarding the pharmacy's potential red flags and its alleged role in diversion of controlled substances. For example, a June 2014 brief included testimony, taken during a deposition, from an individual who had prescriptions filled at Tug Valley, and is reproduced below:[508]

> **This description of the environment at Tug Valley was provided by Respondent [redacted]**
>
> **" So, I would go in and I would wait for so long. And there were so many people. So many people. I mean, there was such a line. And there were people coming in from everywhere. I mean, I noticed and I heard there were people coming from like Ohio. There were people coming in from like way over in West Virginia. I can't remember the name of it. And there were people slumped over. I mean, totally out of their mind. I know when I seen them, somebody like that, I know...And they were just like selling drugs outside of the place...I kept hearing people, you know, stating where they can get this and that and how much for, [redacted], J.A. 1374.**

According to the same filing, the owner of Tug Valley Pharmacy testified in a deposition that the pharmacy filled between 150 to 200 prescriptions per day from the Mountain Medical Center,[509] a facility shut down following a federal raid in 2010.[510]

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[506] *Id.*

[507] *See Shaun Collins, et al. v. Tug Valley, LLC, et al.* No. 10-C-251 (Mingo County, W.Va. Circuit Court) (Feb. 18, 2014) *available at* http://www.courtswv.gov/supreme-court/calendar/2015/briefs/march15/14-0144order.pdf.

[508] *Tug Valley Pharmacy et al. v. All Plaintiffs Below* No. 14-0144 at 12 (W. Va. June 2014) (Respondents' Brief) *available at* http://www.courtswv.gov/supreme-court/calendar/2015/briefs/march15/14-0144respondent.pdf.

[509] *Tug Valley Pharmacy et al. v. All Plaintiffs Below* No. 14-0144 at 12 (W. Va. June 2014) (Respondents' Brief) *available at* http://www.courtswv.gov/supreme-court/calendar/2015/briefs/march15/14-0144respondent.pdf.

[510] Lawrence Messina, *W.Va. doctor defends raided pain clinic*, CHARLESTON GAZETTE-MAIL, Apr. 14, 2010, https://www.wvgazettemail.com/news/w-va-doctor-defends-raided-pain-clinic/article_e9099268-dbff-5164-bf89-b562b0ceea39.html.

On July 23, 2015, McKesson's Director of Regulatory Affairs approved Tug Valley as a customer. The Regulatory Investigative Report accompanying the decision referenced Miami-Luken's decision to cease all medication sales to Tug Valley, noting "[i]t was later learned that Tug Valley Pharmacy had experienced credit issues thus the reasoning behind the termination by the wholesaler."[511] The report also stated that the pharmacy was named as a defendant in a civil lawsuit in West Virginia state court, and noted that the lawsuit "allows patients who have become addicted to opiate medications to sue their prescribing physician and/or dispensing pharmacy for monetary damages[,]" making reference to the hyperlinks provided in the May 18, 2015 due diligence report.[512]

The Committee asked McKesson whether it obtained more information on, or asked the pharmacy's owner about, the ligation prior to approving Tug Valley as a customer.[513] In response, McKesson told the Committee:

> To the best of McKesson's current understanding, McKesson did not have a discussion with the owner regarding the pending litigation against the pharmacy. During the onboarding review, McKesson considered the litigation. McKesson found that the litigation had been ongoing for several years; that the pharmacy and its owner/pharmacist continued to have active licenses from the State of West Virginia; that there were no known disciplinary actions related to the litigation or other relevant matters; and that the pharmacy had an active DEA registration.[514]

On January 7, 2016, a *CBS News* report focused on the role wholesale distributors may have played in exacerbating the opioid epidemic in West Virginia prominently featured Tug Valley.[515] The next day, January 8, 2016, McKesson suspended Tug Valley's ability to purchase controlled substances.[516]

A Regulatory Investigative Report dated January 8, 2016 and supporting the suspension cited the litigation pending against Tug Valley Pharmacy—and featured in the *CBS News* report—as the impetus for McKesson's decision to suspend the pharmacy.[517] The Regulatory Investigative Report is reproduced in its entirety below:

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[511] McKesson Corp., Regulatory Investigative Report – Tug Valley Pharmacy, July 23, 2015 (On file with Committee).
[512] *Id.*
[513] E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to McKesson Corp. (July 31, 2018 11:10 am) (On file with Committee).
[514] E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee).
[515] Jim Axelrod and Ashley Velie, *Drug distributors under fire in West Virginia painkiller epidemic*, CBS NEWS, Jan. 7, 2016, https://www.cbsnews.com/news/drug-distributors-under-fire-in-west-virginia-painkiller-epidemic/.
[516] McKesson Corp., Regulatory Investigative Report – Tug Valley Pharmacy, Jan. 8, 2016 (On file with Committee).
[517] *Id.*

McKESSON

McKesson's Controlled Substance Monitoring Program
Regulatory Investigative Report

**Date of Final Report: January 8, 2016**

**By:** [redacted]

**Report RE: Suspension of Controlled Substances**

**Customer's Name: Tug Valley Pharmacy**

**Customer's DEA Number:** [redacted]

**DETAILS**

Tug Valley Pharmacy is an existing McKesson customer located at 54 West 2nd Avenue, Williamson, WV 25661. In light of a recent news article concerning Tug Valley Pharmacy and McKesson's re-evaluation of this customer, a decision to suspend Tug Valley's Pharmacy's ability to order controlled substances was rendered.

On January 8, 2016, Sr. DRA [redacted] notified DRA [redacted] of an Internet article he had seen referencing Tug Valley Pharmacy, a McKesson customer. This article, http://www.cbsnews.com/news/drug-distributors-under-fire-in-west-virginia-painkiller-epidemic/ dated January 7, 2016, from CBS News noted that Tug Valley Pharmacy was being sued for negligently filling prescriptions. Records indicated that Tug Valley Pharmacy filled more than 150 prescriptions daily from one clinic alone.

This case is based on a recent decision naming Tug Valley Pharmacy as a defendant, Tug Valley Pharmacy et al v All Plaintiffs (2015 W.Va.). In this case, the State of West Virginia Supreme Court ruled that opiate dependent patients in West Virginia may sue those providers and pharmacies who prescribed and dispensed the opiates, thus causing the patients' addiction to these medications.

The court also ruled while the patients are partially responsible for their own addictions and may have committed illegal acts to obtain the controlled substances, the providers also engaged in questionable activities which may have factored in their addictions.

This court ruling will allow patients to sue civilly and task juries to allocate fault to both patients and providers for causing addiction.

**LICENSE & REGISTRATION REVIEW**

Not applicable.

**BACKGROUND SEARCH**

Not applicable.

**CUSTOMER'S CORRESPONDING RESPONSIBILITY**

Not applicable.

**ON-SITE REVIEW**

Not applicable.

**PURCHASE HISTORY REVIEW**

Not applicable.

**MISCELLANEOUS**

Not applicable.

**CONCLUSION/RECOMMENDATION**

Because of information contained in news article received on January 8, 2016, [redacted] suspended the pharmacy's ability to order controlled substances.

In addition, on January 8, 2016, [redacted] notified Tug Valley Pharmacy owner [redacted] of the decision to suspend.

As stated above, however, McKesson not only had information on this litigation, but also took it into consideration, when it made the decision to approve Tug Valley as a customer in July 2015.[518]

**FINDING:** **McKesson established a business relationship with Tug Valley Pharmacy in July 2015, despite knowledge of pending litigation against the pharmacy related to the alleged diversion of controlled substances. McKesson did not address the litigation with the pharmacy's owner while conducting its due diligence. McKesson later cited the litigation as the reason it suspended Tug Valley's ability to purchase controlled substances after the pharmacy and litigation were featured on *CBS News* in January 2016.**

[518] *See* McKesson Corp., Regulatory Investigative Report – Tug Valley Pharmacy, July 23, 2015 (On file with Committee). *See also* McKesson Corp., Due Diligence Report – Tug Valley Pharmacy, May 18, 2015 (On file with Committee) and E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee).

Less than two weeks later, on January 20, 2016, Tug Valley filed suit against McKesson in West Virginia state court over the suspension, arguing, among other things, that McKesson's decision violated the terms of their contract, and requesting the court to order McKesson to continue selling controlled substances to Tug Valley.[519] To support the company's decision to suspend Tug Valley's ability to purchase controlled substances, McKesson's Senior Director of Regulatory Affairs submitted an affidavit to the West Virginia court, stating:

> As part of my own efforts, I reviewed a brief in the Mingo County lawsuit against Tug Valley Pharmacy. In that lawsuit, plaintiffs are suing Tug Valley Pharmacy, other pharmacies, and doctors for causing their addiction to opiates. I learned from the brief that Tug Valley Pharmacy's owner, [redacted], testified that he filled more than 150 prescriptions daily from one pain clinic alone. I also learned from that brief that a pharmacist testified that Tug Valley Pharmacy was improperly filing prescriptions for class 3 and 4 narcotics.[520]

The affidavit also stated that, based on this information, "continued shipments to Tug Valley Pharmacy put McKesson in jeopardy of being noncompliant with federal and/or state laws and regulations concerning the distribution of controlled substances."[521] Such an assessment raises the question of why McKesson did not flag this issue earlier since, as discussed above, McKesson referenced the litigation involving Tug Valley and provided hyperlinks to relevant court documents in its Regulatory Investigative Report just days after receiving Tug Valley's new customer application.[522] The litigation was also referenced when McKesson elected to onboard Tug Valley as a customer in July 2015.[523]

Press reports indicate that a West Virginia judge scheduled a hearing on January 29, 2015 to hear Tug Valley's claims against McKesson, but the hearing was canceled after the pharmacy withdrew its lawsuit.[524]

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[519] *Tug Valley Pharmacy v. McKesson Corporation* No. 16-C-64 (Kanawha County, W.Va. Circuit Court) (Jan. 20, 2016) (Emergency Verified Petition for Ex Parte Temporary Restraining Order and Preliminary Injunction) (On file with Committee).

[520] *Tug Valley Pharmacy v. McKesson Corporation* No. 16-C-64 (Kanawha County, W.Va. Circuit Court) (Jan. 25, 2016) (Affidavit of [Senior Director of Regulatory Affairs, McKesson Corp.]) (On file with Committee).

[521] *Tug Valley Pharmacy v. McKesson Corporation* No. 16-C-64 (Kanawha County, W.Va. Circuit Court) (Jan. 25, 2016) (Affidavit of [Senior Director of Regulatory Affairs, McKesson Corp.]) (On file with Committee) (internal quotation marks omitted).

[522] *See* McKesson Corp., Due Diligence Report – Tug Valley Pharmacy, May 18, 2015 (On file with Committee).

[523] *See* McKesson Corp., Regulatory Investigative Report – Tug Valley Pharmacy, July 23, 2015 (On file with Committee).

[524] Kate White, *After lawsuit, drug company shuts off supply to Mingo pharmacy*, CHARLESTON GAZETTE-MAIL, Feb. 3, 2016, https://www.wvgazettemail.com/business/after-lawsuit-drug-company-shuts-off-supply-to-mingo-pharmacy/article_e874be9d-16b1-5f7c-8829-b3250df21055.html.

### *ii. McKesson's Second Engagement with Tug Valley Pharmacy*

McKesson's suspension of Tug Valley was not the end of the business relationship, however. On February 4, 2016, approximately two weeks after Tug Valley sued McKesson, , McKesson received a new customer application from the pharmacy, representing that it was under new ownership.[525] A review of the pharmacy questionnaire, included with the application, shows that the new owner was unable to answer many of the questions posed therein, simply supplying question marks as answers when asked about the types of facilities the pharmacy serves and how the pharmacy receives customers.[526] Portions of the pharmacy questionnaire are reproduced below:

d. How do new prescriptions come to the pharmacy (please express as a percentage)? ?

Walk-in _____

Phone _____

Fax / E-prescribing _____

Internet _____

g. Pain Management Clinics ?

i. Does pharmacy provide direct service to Pain Management Clinics?
☐Yes ☐No

ii. If yes, what % of scripts does the pharmacy receive from pain management clinics? _____

iii. If yes, what % of the pain management scripts are for controlled substances? _____

[525] McKesson Corp., Pharmacy Questionnaire – Tug Valley Pharmacy, Feb. 3, 2016 (On file with Committee). It should be noted, and will be discussed later in this report, documents show that the pharmacy's original owner was later discovered to be working at the pharmacy after the change in ownership was reportedly effectuated and even though the original owner was to have no association with Tug Valley Pharmacy, according to a February 29, 2016 Regulatory Investigative Report. *See infra* Section VI (D)(2)(a).

[526] McKesson Corp., Pharmacy Questionnaire – Tug Valley Pharmacy, Feb. 3, 2016 (On file with Committee).

h. Does pharmacy service nursing homes, long term care or hospice facilities? ☐Yes ☐No

i. Is pharmacy located within a medical center or clinic? ☐Yes ☐No

j. Does pharmacy regularly fill controlled substance prescriptions written by out of state providers? ☐Yes ☐No

McKesson policies maintain that upon receipt of a questionnaire, a McKesson Regulatory Affairs Administrator shall review the questionnaire for completeness, and "[n]otify the submitter if the questionnaire is incomplete/illegible or if there are any missing items (e.g., photos or dispensing data)."[527] McKesson's policies also maintain that "[i]nvalid/inaccurate/inconsistent answers on questionnaire(s)" are "red flags" that may be a cause for concern, and "when 'red flags' are identified they are reviewed to ensure appropriate due diligence."[528]

A Regulatory Investigative Report from August 2016 stated with respect to the customer questionnaire, McKesson "found no 'red flags' or anomalies" regarding Tug Valley's new ownership.[529] The report stated, in relevant part:

> local physicians only. The customer questionnaire dated February 3, 2016 and February 15, 2016 found no "red flags" or anomalies regarding the new ownership of JCL Management and Consulting, dba: Tug Valley Pharmacy.

The Committee asked McKesson whether the company considered the new owner's inability to answer basic questions about the pharmacy on the questionnaire as a red flag.[530] McKesson replied, in part, "[a]s this pharmacy was an existing McKesson customer, the regulatory team was familiar with the pharmacy and was aware, for example, that the pharmacy was not located within a medical clinic."[531] The Committee also asked McKesson, its existing

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[527] McKesson Corp., ISMC Controlled Substance Monitoring Program Operating Manual, 11 (Effective Date June 1, 2015 and last revised May 17, 2017) (On file with Committee).

[528] McKesson Corp., McKesson CSMP "Red Flags," May 2015 (On file with Committee).

[529] McKesson Corp., Regulatory Investigative Report – JCL Management and Consulting, dba: Tug Valley Pharmacy, Aug. 24, 2016 (On file with Committee).

[530] *See* E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to McKesson Corp. (July 31, 2018 11:10 am) (On file with Committee).

[531] E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee). McKesson's response to the Committee's question also referred the Committee to a February 29, 2016 Regulatory Investigative Report which documents a conversation McKesson's Director Regulatory Affairs had with the new owner on February 26, 2016, discussed in more detail later in this case study, and that this "report notes specifically that [McKesson's Director Regulatory Affairs] reviewed the questionnaire

knowledge of the pharmacy notwithstanding, whether an owner, or even a prospective owner, of a pharmacy should have knowledge of the pharmacy's basic characteristics and operations.[532] In response, McKesson did not directly address the Committee's question, instead directing the Committee to its prior response, which is cited above.[533]

With respect to the question marks provided on pharmacy questionnaire, McKesson later told the Committee, "[i]t is not clear what [new owner] meant by adding question marks, and the possibilities include that he was unsure how to interpret the questions or how to answer them."[534] It strains credulity, however, that the owner of a pharmacy or even a prospective owner of a pharmacy would be unable to answer or could misinterpret a yes or no question such as "[i]s pharmacy located within a medical center or clinic?"

In addition, documents produced to the Committee indicate that the new owner provided inconsistent corporate names on the customer application and the pharmacy questionnaire.[535] Documents also indicate that the new owner listed his own home address incorrectly on the customer application in addition to repeatedly providing the wrong zip code for Williamson, West Virginia, the location of Tug Valley Pharmacy.[536]

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| **FINDING:** | **In February 2016, McKesson received a new customer application from Tug Valley Pharmacy, representing that it was under new ownership. The application contained multiple errors. McKesson also received a pharmacy questionnaire in which the new owner was unable to answer basic questions about the pharmacy.** |

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with [new owner] and the report indicates that [Director of Regulatory Affairs] discussed with [new owner] topics that were noted with a question mark in the questionnaire." In later correspondence with the Committee, and with respect to this conversation, however, McKesson stated, "McKesson is not aware that it discussed the reasons why the pharmacy owner was unable to respond to the "question mark" answers at the time the questionnaire was filled out." E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 12, 2018 4:22 pm) (On file with Committee). McKesson also told the Committee, "a McKesson employee specifically discussed with [the new owner] the questionnaire and his responses, and so whatever the reasons for [new owner's] manner of filling out the form, McKesson did talk through the answers with the applicant, as memorialized in the February 29, 2016 Regulatory Investigative Report." Letter from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce, Oct. 19, 2018 (On file with Committee).

[532] *See* E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to McKesson Corp. (Oct. 4, 2018 10:17 am) (On file with Committee).

[533] *See* E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 12, 2018 4:22 pm) (On file with Committee).

[534] Letter from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce, Oct. 19, 2018 (On file with Committee).

[535] *See* McKesson Corp., Pharmacy Questionnaire – Tug Valley Pharmacy, Feb. 3, 2016 (On file with Committee) and McKesson Corp., Customer Application, Feb. 3, 2016 (On file with Committee). The Committee's research also indicates the organizing documents for both corporate entities, listed on the February 3, 2016, customer application and pharmacy questionnaire, were drafted on February 4, 2016, and filed with the Kentucky Secretary of State on February 8, 2016. *See* Articles of Organization of Eastridge General Management, LLC, Ky. Sec'y of State, Feb. 4, 2016, *available at* https://app.sos.ky.gov/corpscans/86/0943686-06-99999-20160208-KLC-6375884-PU.pdf. *See also* Articles of Organization of JCL Management and Consulting, LLC, Ky. Sec'y of State, Feb. 4, 2016, *available at* https://app.sos.ky.gov/corpscans/84/0943684-06-99999-20160208-KLC-6375878-PU.pdf.

[536] McKesson Corp., Customer Application, Feb. 3, 2016 (On file with Committee).

Documents also indicate that at the time of purchase, the new owner of Tug Valley Pharmacy was of fairly limited financial means[537] and that another individual listed as a guarantor on the customer application likely provided $200,000 to cover the entire down payment for the purchase.[538] In an e-mail to the new owner, a McKesson Retail Sales Manager requested, among other things, the contract between the new owner and the guarantor related to the purchase of Tug Valley.[539] The documents produced to the Committee indicate that McKesson received a fax transmitting information related to the purchase of Tug Valley Pharmacy. Included in this fax was a document purportedly providing the contract between the new owner and the guarantor.[540] This contract, is undated and does not contain any signatures. The Committee has seen no indication to suggest that McKesson made any further attempts to obtain an executed contract between the new owner and the guarantor. The contract is reproduced in its entirety below:

FEB-12-2016 17:19 From: [redacted] Page:7/34

[redacted]

The contract between [redacted] and [redacted] is as followed.

[redacted] (South Fork General Management) will give 200,000 for operating capital. In return South Fork General Management will receive 45% of the monthly net profit. The percentage is done so that on the occasion a reimbursement check circle from insurance companies fall unfavorably I will not have to dip into operating capital to pay the management fees that South Fork will be providing.

[537] Specifically, according to a document supplied by the new owner to McKesson at the time of purchase, the new owner represented that he owed more in outstanding personal loans than he had cash on hand, in addition to having a mortgage. This document appears to have been produced to McKesson in response to an e-mail sent by a McKesson Retail Sales Manager in which the Retail Sales Manager stated, among other things, "[o]ur credit guy would like your personal financial statement (Assets and liabilities, cash on hand)." E-Mail from Retail Sales Manager, McKesson Corp., to [redacted] (Feb. 8, 2016 4:46 pm) (On file with Committee).

[538] At the time of purchase, this individual owned other pharmacies that were also McKesson customers. *See* Letter from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce, Oct. 19, 2018 (On file with Committee). As stated, this individual was listed as the guarantor on the February 3, 2016 McKesson customer application. Based on the documents provided to the Committee, this individual was not a guarantor to the underlying sale of the pharmacy. Rather, pursuant to a Guaranty Agreement, the new owner, in his individual capacity, was responsible for the repayment of the loan that was obtained to facilitate the purchase of the pharmacy. *See* McKesson Corp., Due Diligence Document – Tug Valley Pharmacy – Promissory Note and Guaranty Agreement, Feb.11, 2016 (On file with Committee).

[539] *See* E-Mail from Retail Sales Manager, McKesson Corp., to [redacted] (Feb. 8, 2016 4:46 pm) (On file with Committee).

[540] *See* McKesson Corp., Due Diligence Document – Tug Valley Pharmacy (On file with Committee).

The documents faxed to McKesson related to the sale of Tug Valley Pharmacy also indicate that the new owner acquired the pharmacy through a financing arrangement with the former owner wherein the former owner financed the sale of the pharmacy through a corporation of which he was the sole shareholder, and retained a security interest in the pharmacy as collateral for making the loan to the new owner.[541] This financing arrangement meant that, should the new owner default on his loan, ownership of the pharmacy would revert back to the prior owner. As stated above, under the former owner, McKesson terminated Tug Valley Pharmacy as a customer on January 8, 2016 after the pharmacy was featured on the *CBS News* related to allegations about its opioid dispensing practices. McKesson policies advise that "a questionable change in ownership" is a potential "red flag" of concern.[542] In addition, the documents related to the sale of Tug Valley Pharmacy, and produced to the Committee, reference a promissory note for the repayment of an outstanding balance of $160,000. The Committee requested that McKesson produce the promissory note, but the company was unable to do so.[543]

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| **FINDING:** | **In February 2016, Tug Valley Pharmacy was sold through a financing arrangement under which the former owner retained a security interest in the pharmacy as collateral for making a loan to the new owner to facilitate the purchase.** |

According to a February 29, 2016 Regulatory Investigative Report, McKesson elected to onboard Tug Valley as a customer again on the same day its Director of Regulatory Affairs conducted an interview with the new owner of Tug Valley.[544] The report indicates that McKesson performed internet searches on the pharmacy and its personnel, and verified that the new owner's pharmacy technician's license was active.[545] The report also indicates that the new owner was asked about any experience he had owning or managing a pharmacy, noting that he was the manager of another pharmacy which was also a McKesson customer at the time.[546] The pharmacy questionnaire discussed above was reviewed as well.[547]

With respect to the Director of Regulatory Affairs' interview and review of the pharmacy questionnaire with the new owner, McKesson told the Committee:

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[541] Specifically, the former owner financed the sale of the pharmacy through a corporation of which he was the sole shareholder. *See* McKesson Corp., Due Diligence Document – Tug Valley Pharmacy – Promissory Note and Guaranty Agreement, Feb.11, 2016 (On file with Committee); McKesson Corp., Due Diligence Document – Tug Valley Pharmacy – Security Agreement, Feb.11, 2016 (On file with Committee); McKesson Corp., Due Diligence Document – Tug Valley Pharmacy – Agreement, Feb. 11, 2016 (On file with Committee).
[542] McKesson Corp., McKesson CSMP "Red Flags," May 2015 (On file with Committee).
[543] *See* E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Nov. 29, 4:55 pm) (On file with Committee).
[544] McKesson Corp., Regulatory Investigative Report – Tug Valley Pharmacy II, Feb. 29, 2016 (On file with Committee).
[545] *Id.*
[546] *Id.*
[547] *Id.*

> Furthermore, regulatory personnel did have a follow-up discussion with [new owner] regarding the questionnaire and his background that is documented in a February 29, 2016 Regulatory Investigative Report. The report notes specifically that [McKesson's Director of Regulatory Affairs] reviewed the questionnaire with [new owner] and the report indicates that [Director of Regulatory Affairs] discussed with [the new owner] topics that were noted with a question mark in the questionnaire. For example, the report indicates there was discussion with [new owner] about the pharmacy's service area, whether the pharmacy will fill controlled substance prescriptions from pain management providers, whether the pharmacy is located in a medical center or medical clinic, and whether the pharmacy will service nursing homes, long term care, or hospice facilities.[548]

Despite McKesson's policies indicating that invalid answers are "red flags," the report makes no mention of whether McKesson questioned why the new owner was unable to answer multiple questions on the pharmacy questionnaire.[549] The Committee highlighted the latter point to McKesson.[550] In response, McKesson stated, "McKesson is not aware that it discussed the reasons why the pharmacy owner was unable to respond to the 'question mark' answers at the time the questionnaire was filled out."[551]

| FINDING: | **Despite McKesson policies stating that invalid, inaccurate, or inconsistent answers on a questionnaire are a cause for concern, it does not appear that McKesson sought further explanation from the pharmacy's new owner as to why he was unable to answer several basic questions about the pharmacy as posed in McKesson's pharmacy questionnaire.** |
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The February 2016Regulatory Investigative Report also noted that "Tug Valley Pharmacy was a former McKesson customer until January 8, 2016, when McKesson terminated its ability to order controlled substances because of derogatory information regarding the pharmacy's controlled substance dispensing practices."[552] The report indicates that the new owner was questioned about Tug Valley's previous owner who sued McKesson after the company suspended the pharmacy's ability to purchase controlled substances after being featured on the *CBS News*, stating, "[Tug Valley's new owner] said that former owner [redacted] has no association with Tug Valley Pharmacy II. [New owner] said he did retain other employees from the pharmacy including pharmacy technicians and cashiers."[553]

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[548] E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 1, 2018 2:05 pm) (On file with Committee).
[549] *See* McKesson Corp., Regulatory Investigative Report – Tug Valley Pharmacy II, Feb. 29, 2016 (On file with Committee).
[550] *See* E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to McKesson Corp. (Oct. 4, 2018 10:17 am) (On file with Committee).
[551] E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 12, 2018 4:22 pm) (On file with Committee).
[552] McKesson Corp., Regulatory Investigative Report – Tug Valley Pharmacy II, Feb. 29, 2016 (On file with Committee).
[553] *Id.*

However, as discussed previously, documents produced to the Committee indicate the former owner did, in fact, retain an association to the pharmacy through the financing arrangement made between the former owner and the new owner, and known to McKesson. The February 2016 report does not mention, nor has the Committee seen any indication, that McKesson asked about, or had concerns regarding, the former owner's retention of a security interest in the pharmacy or the fact that he provided the financing arrangement to facilitate the pharmacy's sale.

**FINDING:** **In February 2016, Tug Valley Pharmacy's new owner told McKesson that the former owner no longer had an association with the pharmacy. Not only was this statement not true, but McKesson was in possession of a document at the time of its 2016 approval indicating that the former owner maintained a security interest in the pharmacy. The Committee has seen no indication to suggest that McKesson asked the pharmacy about the former owner's continuing security interest.**

As will be discussed in greater detail later in this report, despite the new owner's representation that the former owner would have no association with the pharmacy, documents show that, in addition to the security interest retained in the pharmacy, the former owner also worked at the pharmacy for an indeterminate period of time after the pharmacy was reinstated by McKesson.[554]

The Regulatory Investigative Report that accompanied McKesson's decision to onboard Tug Valley as a customer again also references a Power of Attorney authorizing the new owner to use the pharmacy's existing DEA registration number, and indicates McKesson's Director of Regulatory Affairs asked the new owner whether the "change of ownership had been properly vetted for approval with the local DEA office in Charleston, WV."[555] In response to McKesson's question, the report indicates the new owner represented that the DEA informed him agency approval was not required for this transaction, noting:

> [New Owner] stated that on the day the power of attorney was executed, February 11, 2016, he contacted [redacted], a DEA Diversion Investigator, with DEA – Charleston, telephone # [redacted]. According to [new owner], [redacted] said that [new owner] didn't need DEA's permission for this type of acquisition. [New owner] added that based on [redacted's] comment, he surmised the change of ownership was authorized by DEA.[556]

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[554] *See infra* Section VI(D)(2)(a).
[555] McKesson Corp., Regulatory Investigative Report – Tug Valley Pharmacy II, Feb. 29, 2016 (On file with Committee); *see also* Limited Power of Attorney, Feb. 11, 2016 (On file with Committee).
[556] McKesson Corp., Regulatory Investigative Report – Tug Valley Pharmacy II, Feb. 29, 2016 (On file with Committee).

DEA regulations allow for a transfer of registration only if certain conditions are met and require the DEA's written consent.[557] The documents produced to the Committee give no indication to suggest that McKesson contacted the DEA to verify whether the agency did in fact approve this transaction. Considering Tug Valley's history, the Committee asked McKesson whether it contacted the DEA itself to obtain the written approval from DEA authorizing the new owner to use Tug Valley's existing DEA registration.[558] In response, McKesson told the Committee:

> It is McKesson's general practice to request, from the prospective customer or individual who is selling their pharmacy, any communications with DEA regarding the sale and transfer. In McKesson's experience, DEA rarely issues written approval of sales. As to Tug Valley specifically, as recorded in the [February 29, 2016 Regulatory Investigative Report], McKesson asked the new owner of Tug Valley if he had contacted DEA. The new owner indicated he had spoken to a DEA Diversion Investigator who was known to McKesson's Regulatory Affairs personnel. As noted in the [February 29, 2016 Regulatory Investigative Report], the investigator informed the new owner that DEA permission was unnecessary in this instance. We understand that this is consistent with DEA's typical practice in these circumstances.[559]

The DEA told Committee staff, while the manner by which DEA communicates its approval may vary in certain circumstances, agency approval is always required when transferring or authorizing the use of an existing DEA registration.[560] In an e-mail to Committee staff, DEA stated:

> DEA registrations are not regarded as being 'transferable,' but 21 CFR 1301.52 is clear on what registrants must do if they wish to have DEA consider a proposal to transfer a registration. Pursuant to the regulations, they must submit a request to DEA in writing (both to the head of the Diversion Control Program and the Special Agent in Charge). The intent of this formal process is to ensure that any such transfer remains consistent

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[557] Specifically, the DEA regulations governing the transfer of registration require: "[n]o registration or any authority conferred thereby shall be assigned or otherwise transferred except upon such conditions as the Administration may specifically designate and then only pursuant to written consent. Any person seeking authority to transfer a registration shall submit a written request, providing full details regarding the proposed transfer of registration, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration." *See* 21 CFR §1301.52(b).

[558] *See* E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to McKesson Corp. (Oct. 4, 2018 10:17 am) (On file with Committee).

[559] E-Mail from Counsel to McKesson Corp., to Staff, H. Comm. on Energy and Commerce (Oct. 12, 2018 4:22 pm) (On file with Committee).

[560] Phone call between Staff, U.S. Drug Enforcement Admin. and Staff, H. Comm. on Energy and Commerce (Oct. 23, 2018).

> with the DEA's statutory obligation to ensure that the registration is consistent with the public interest factors.[561]

The response provided by McKesson suggests that it did not contact the DEA itself to ensure that the agency had approved the new owner's use of Tug Valley's existing DEA registration, instead relying on the representation of the new owner. Failing to independently contact the DEA and verify whether the agency approved the transfer of a registration to dispense controlled substances creates a serious risk that a distributor could facilitate drug diversion by providing controlled substances to a person that has not been vetted by the appropriate regulatory authorities. In July 2016, McKesson finally received notice that the pharmacy obtained a new DEA registration number.[562]

As will be discussed in more detail in section VI(D)(2)(a), McKesson suspended Tug Valley Pharmacy's ability to purchase controlled substances for a second time on February 28, 2018. Had McKesson performed additional due diligence with respect to red flags associated with the pharmacy, the company may have identified information that could have prompted it to deny the pharmacy's 2016 application, thereby avoiding entering a relationship with an owner whom the company later took action against, attributable to his deceit. Not following up on, and documenting its analysis of, red flags concerning a prospective or existing customer undermines the completeness and utility of a distributor's due diligence file.

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[561] E-Mail from Staff, U.S. Drug Enforcement Admin., to Staff, H. Comm. on Energy and Commerce (Nov. 16, 2018 4:35 p.m.) (On file with Committee).

[562] McKesson Corp., Regulatory Investigative Report – JCL Management & Consulting, dba: Tug Valley Pharmacy, July 27, 2016 (On file with Committee).

### d. *Case Study on AmerisourceBergen: Evaluation of a Pharmacy's Prescribing Physicians*

When conducting prospective and existing customer due diligence, a distributor may obtain information regarding a pharmacy's prescribing physicians which raises concerns about possible diversion, thereby meriting additional examination. Similar to other aspects of the due diligence process, when a distributor does identify potential red flags related to a pharmacy's prescribing physicians, it should seek further explanation from the pharmacy in addition to performing its own substantive analysis, documenting both. Doing so offers distributors the chance to make a better-informed decision regarding a pharmacy's application, and also provides a more robust record for future reviews.

Westside Pharmacy, located in Oceana, West Virginia, had a population of 1,394 in 2010.[563] Oceana is located in Wyoming County, West Virginia, which, according to media reports, was determined to have the highest prescription overdose death rate in the nation, on average, between 1999 and 2014,[564] in addition to seeing a 6,973.1 percent increase in drug overdose deaths between 1980 and 2014 which ranked second in the nation.[565] AmerisourceBergen was one of multiple distributors that supplied Westside Pharmacy, which received nearly 8.62 million doses of hydrocodone and oxycodone from all distributors between 2006 and 2016.[566]

#### i. *AmerisourceBergen's Initial Encounter with Westside Pharmacy*

In June 2011, AmerisourceBergen approved Westside Pharmacy as a new customer and agreed to provide the pharmacy with controlled substances.[567] AmerisourceBergen produced 11 total pages of due diligence material to the Committee related to its engagement with Westside Pharmacy in 2011 and 2012.[568]

The documents produced in the due diligence material include license verifications with the DEA and the West Virginia Board of Pharmacy, photographs that were taken at the pharmacy, and a Retail Pharmacy Questionnaire. The due diligence documents also included a document titled 'Westside Pharmacy Pain Doctors,' which was simply a list of names and addresses of six doctors, two of which were located outside of West Virginia. The 'Westside

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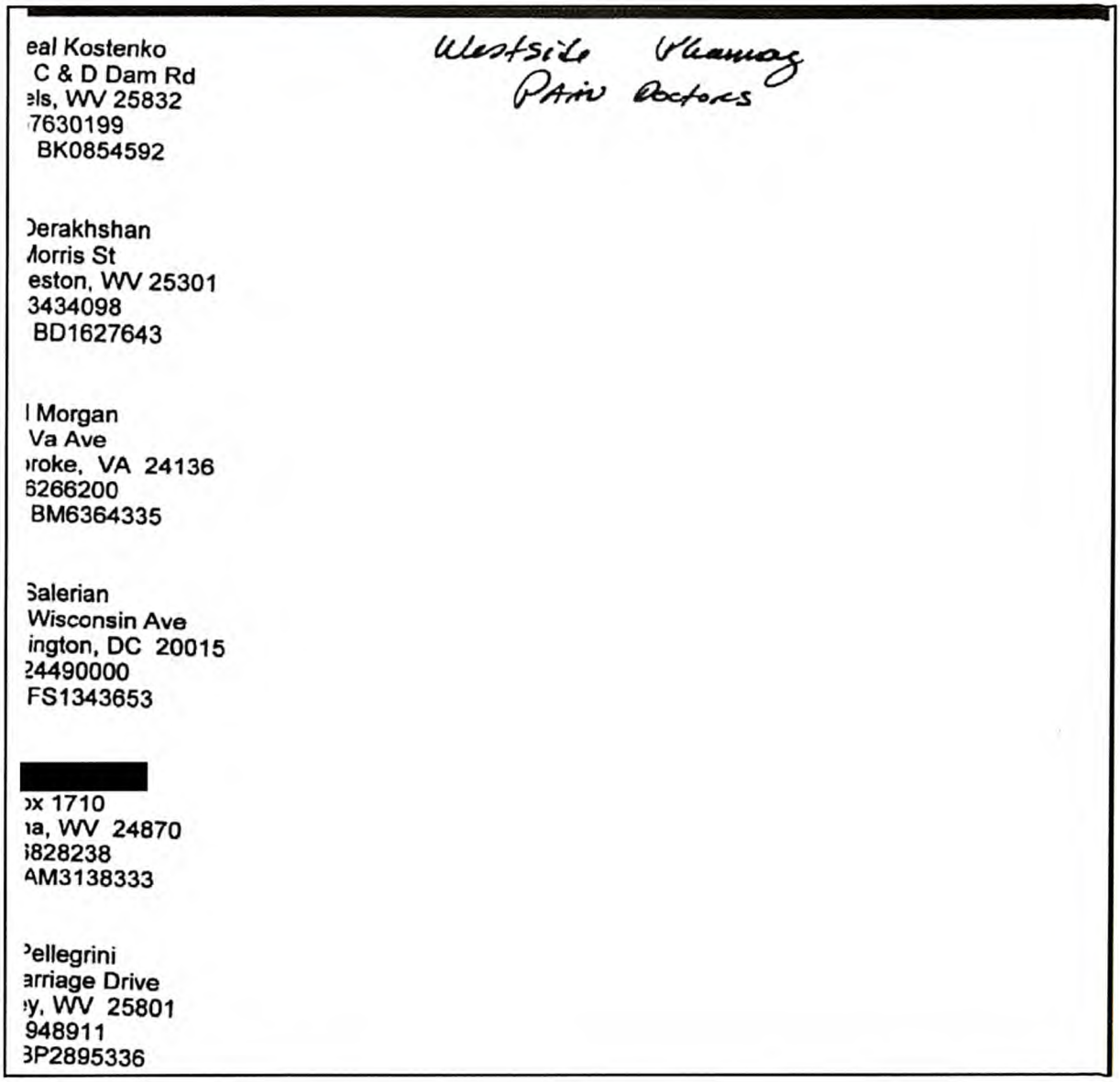
[563] American FactFinder, *Oceana town, West Virginia* (https://factfinder.census.gov).
[564] *See* Wendy Holdren, *Report shows Wyoming County worst in country for prescription drug deaths*, REGISTER-HERALD, Aug. 21, 2016, https://www.register-herald.com/news/report-shows-wyoming-county-worst-in-country-for-prescription-drug/article_123649b7-d708-5896-8cd6-040aae835ebd.html.
[565] *See* Jen Christensen, *Drug deaths rose 8,370% in some US counties over 34 years,* CNN, Mar. 13, 2018, https://www.cnn.com/2018/03/13/health/drug-deaths-increase-study/index.html.
[566] U.S. Drug Enforcement Admin., ARCOS Data (On file with Committee).
[567] E-Mail from Corporate Security & Regulatory Affairs, AmerisourceBergen Corp. to NRCM, AmerisourceBergen Corp. (June 13, 2011 4:59 pm) (On file with Committee).
[568] *See* AmerisourceBergen Corp., Westside Pharmacy Due Diligence Documents (On file with Committee); *see also* E-Mail from Counsel to AmerisourceBergen Corp., to Staff, H. Comm. on Energy and Commerce (Aug. 17, 2018 4:46 pm) (On file with Committee).

Pharmacy Pain Doctors' document is reproduced in its entirety below and in the condition that it was produced to the Committee:[569]



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Westside Pharmacy
Pain Doctors

[569] AmerisourceBergen Corp., Westside Pharmacy Due Diligence Document (On file with Committee). The Committee asked AmerisourceBergen whether the document produced to the Committee was the most complete copy in the company's records, and if not, the Committee requested AmerisourceBergen provide the Committee with an updated copy. *See* E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to AmerisourceBergen Corp. (Nov. 1, 2018 11:41 am) (On file with Committee). In response, AmerisourceBergen told the Committee, "[t]he document produced at [bates number] appears to be a document provided to ABDC by the pharmacy. From the best of our due diligence efforts, ABDC appears to only have it captured in this form at this time, which could be the result of how is [sic] was copied or input at the time. In any case, we could not find a better a [sic] copy in the records available." E-Mail from Counsel to AmerisourceBergen Corp., to Staff, H. Comm. on Energy and Commerce (Nov. 2, 2018 5:16 pm) (On file with Committee).

One doctor, Dr. David Morgan, had an address in Pembroke, VA while another, Dr. Alen Salerian,[570] had an address located in located in Washington, D.C. Pembroke, VA and Washington, D.C. are a four-hour and an eleven-and-a-half-hour round-trip drive from the pharmacy, respectively. In total, five of the six doctors listed on the 'Westside Pharmacy Pain Doctors' document included in AmerisourceBergen's 2011 due diligence file have either been subsequently convicted of, or indicted on, criminal charges related to their controlled substance prescribing or are currently under federal investigation.[571]

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| **FINDING:** | **AmerisourceBergen's due diligence documents for Westside Pharmacy included a list of six "Pain Doctors." Two of the doctors were located a four-hour and eleven-and-a-half-hour round-trip drive from the pharmacy respectively. Five of the six doctors have either been subsequently convicted of, or indicted on, criminal charges related to their controlled substance prescribing, or are currently under federal investigation.** |

The Committee requested that AmerisourceBergen provide any due diligence documents that would demonstrate the company's efforts to examine why certain physicians were located such substantial distances from the pharmacy.[572] In response to the Committee's request, AmerisourceBergen was unable to produce any documents that would demonstrate it undertook such an examination.[573] Instead, the company referred the Committee to the 11-page due

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[570] After his office and home were raided by federal agents in March 2011, a grand jury indicted Dr. Alen Salerian in April 2013 on 36 charges, alleging that he conspired to distribute controlled substances without a legitimate medical purpose and beyond the bounds of medical practice. *See* Press Release, Federal Bureau of Investigation, Washington, D.C. Doctor Indicted on Prescription Drug Distribution Charges (Apr. 25, 2013), https://archives.fbi.gov/archives/richmond/press-releases/2013/washington-d.c.-doctor-indicted-on-prescription-drug-distribution-charges. The grand jury issued a superseding indictment against Dr. Salerian in June 2013, bringing the total number of charges brought by the government to 144. *See United States v. Salerian*, No. 1:13CR00017, 2 (W.D. Va. Jan. 28, 2014) (Opinion and Order) *available at* http://www.vawd.uscourts.gov/OPINIONS/JONES/1-13cr00017.mot.dismiss.opinion.pdf. The charges against Dr. Salerian were dismissed in 2016, however, after a federal judge determined that he was not mentally competent to stand trial. *See United States v. Salerian*, No. 1:13CR00017 (W.D. Va. Mar. 10, 2016) (Opinion and Order) *available at* http://www.vawd.uscourts.gov/OPINIONS/JONES/1-13cr00017%20dismiss%20op.pdf.

[571] *See* Press Release, Dep't of Justice, U.S. Attorney's Office, S.D. W.Va., Beckley area physician sentenced to 20 years in federal prison for oxycodone crime (Aug. 23, 2017), https://www.justice.gov/usao-sdwv/pr/beckley-area-physician-sentenced-20-years-federal-prison-oxycodone-crime; *United States v. Salerian*, No. 1:13CR00017 (W.D. Va. Mar. 10, 2016) (Opinion and Order) *available at* http://www.vawd.uscourts.gov/OPINIONS/JONES/1-13cr00017%20dismiss%20op.pdf; Jeff Surgeon, *Former Giles County doctor, stripped of license, faces federal criminal probe*, ROANOKE TIMES, Apr. 18, 2017, http://www.roanoke.com/news/local/former-giles-county-doctor-stripped-of-license-faces-federal-criminal/article_ccfcd2ad-684d-52c2-87c0-078f7dff8445.html; Wendy Holdren, *HOPE Clinic doctor Pellegrini pleads guilty in drug case*, REGISTER-HERALD, Apr. 27, 2018, https://www.register-herald.com/news/hope-clinic-doctor-pellegrini-pleads-guilty-in-drug-case/article_f7307f96-4a2e-11e8-8b0d-3307804bc901.html; and Press Release, Dep't of Justice, U.S. Attorney's Office, S.D. W.Va., Charleston doctor pleads guilty to Federal crime involving dispensing fentanyl (Apr. 21, 2016), https://www.justice.gov/usao-sdwv/pr/charleston-doctor-pleads-guilty-federal-crime-involving-dispensing-fentanyl.

[572] *See* E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to AmerisourceBergen Corp. (July 23, 2018 3:13 pm) (On file with Committee).

[573] E-Mail from Counsel to AmerisourceBergen Corp., to Staff, H. Comm. on Energy and Commerce (Aug. 17, 2018 4:46 pm) (On file with Committee).

diligence file and noted "ABDC also received information on prescribing physicians[,]" making reference to the 'Westside Pharmacy Pain Doctors' list that is reproduced above.[574] As indicated, this document, which is an incomplete photocopy, only provides names and addresses, and does not contain any other information that would that indicate AmerisourceBergen performed any additional due diligence. Similarly, the Committee has not seen any indication, nor has it received any documentation to suggest, that AmerisourceBergen questioned the pharmacy as to why it was filling prescriptions for physicians that were located hours away from the pharmacy.

**FINDING: Based on documents provided to the Committee, in 2011, AmerisourceBergen did not investigate why Westside Pharmacy filled prescriptions for physicians located hours away from the pharmacy.**

Publicly available information at the time of AmerisourceBergen's due diligence review also documented disciplinary action taken in 2008 by the Virginia Board of Medicine against Dr. Morgan related to inappropriate prescribing of controlled substances.[575] When asked by the Committee about any due diligence conducted on Dr. Morgan in 2011, AmerisourceBergen responded, "[w]hile the [due diligence] file does not contain details of the searches done on Dr. Morgan, or the other prescribing physicians identified on [the document titled "Westside Pharmacy Pain Doctors"], it appears that in 2011, Dr. Morgan's license to prescribe was clear of any restrictions."[576] To demonstrate this point, AmerisourceBergen cited a July 24, 2009 letter from the Board of Medicine, certifying that Dr. Morgan complied with the terms of the 2008 order.[577] The Committee has not seen any indication, nor has it received any documentation to suggest, that AmerisourceBergen queried the Board or any other sources when it was conducting due diligence on Westside Pharmacy in 2011.

The Committee's review of DEA ARCOS data showed that AmerisourceBergen discontinued supplying Westside Pharmacy with opioids at some point during 2012. The Committee requested that the company provide the reason for this. In response, AmerisourceBergen told the Committee, "[a]fter a comprehensive search, we believe that Westside Pharmacy voluntarily moved its business from ABDC to another wholesaler in late 2012, shortly after ABDC placed stricter limits on its purchasing of controlled substances."[578] The documents produced to the Committee do not contain any information related to any limitations AmerisourceBergen may have imposed on Westside Pharmacy or the pharmacy's apparent decision to discontinue its business relationship with the company.

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[574] *Id.*

[575] *In re: David Lee Morgan, D.O.*, Consent Order, 1-2 (Va. Board of Medicine, Oct. 14, 2008) *available at* http://www.dhp.virginia.gov/Notices/Medicine/0102201292/0102201292Order10142008.pdf. More information regarding Dr. Morgan can be found at *infra* Section VI(A)(2)(d)(ii)(c).

[576] E-Mail from Counsel to AmerisourceBergen Corp., to Staff, H. Comm. on Energy and Commerce (Aug. 17, 2018 4:46 pm) (On file with Committee).

[577] *See* E-Mail from Counsel to AmerisourceBergen Corp., to Staff, H. Comm. on Energy and Commerce (Aug. 17, 2018 4:46 pm) (On file with Committee). *See also* Letter from William L. Harp, M.D., Exec. Dir., Va. Bd. of Md. to David. K. Morgan, D.O., July 24, 2009 (On file with Committee).

[578] Letter from Counsel to AmerisourceBergen Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce et al., May 7, 2018 (On file with Committee).

**FINDING:** **AmerisourceBergen told the Committee that it placed stricter limits on Westside Pharmacy's purchasing of controlled substances in late 2012. The Committee received no documents that reference these limitations or the pharmacy's apparent decision to subsequently end its business relationship with AmerisourceBergen.**

The next year, in 2013, Oceana, West Virginia, where Westside Pharmacy is located, was the subject of a documentary titled "Oxyana" which depicts the toll the opioid epidemic has taken on the West Virginia town.[579] A press report highlighting some of the documentary's findings stated,"[o]ne drug dealer in the film, who likens the situation there to 'the Wild West,' claims to pay a doctor in Washington, D.C., $1,000 to receive a one-month prescription of 450 30mg Oxy pills. That's 15 pills a day. And since a single 30mg Oxy pill sells for $45 on the street, the dealer stands to make $20,250 per 'transaction.'"[580]

### *ii. AmerisourceBergen's Second Encounter with Westside Pharmacy*

In January 2016, AmerisourceBergen approved a new customer application for Westside Pharmacy.[581] The due diligence files make no reference to the pharmacy's prior engagement with Westside Pharmacy, including the company's apparent decision to impose stricter limits on the pharmacy's ability to purchase controlled substances in 2012.[582] When asked by the Committee whether AmerisourceBergen considered the prior engagement, AmerisourceBergen referred the Committee to Westside's 2016 due diligence file.[583] Given that the due diligence file makes no mention of the pharmacy's previous history with the company, the Committee infers that it was not a factor in AmerisourceBergen's analysis.

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[579] *See* Leora Arnowitz, *'Oxyana' premieres at Tribeca Film Festival, gives an up-close look at drug use in West Virginia,* FOX NEWS, Apr. 19, 2013, https://www.foxnews.com/entertainment/oxyana-premieres-at-tribeca-film-festival-gives-an-up-close-look-at-drug-use-in-west-virginia; *see also* Sheila O'Malley, *At the Tribeca Film Festival: A message to you from a West Virginia town ruined by Oxycontin*, POLITICO, Apr. 26, 2013, https://www.politico.com/states/new-york/albany/story/2013/04/at-the-tribeca-film-festival-a-message-to-you-from-a-west-virginia-town-ruined-by-oxycontin-067223; Dave Boucher, *Oceana officials admit drugs pose problem, search for solution*, CHARLESTON GAZETTE-MAIL, May 10, 2013, https://www.wvgazettemail.com/news/oceana-officials-admit-drugs-pose-problem-search-for-solution/article_a22eb20e-79b8-50c1-ae44-e2bd74f4fcbc.html; Dave Boucher, *Small town faces up to film's image of Oxyana*, CHARLESTON GAZETTE-MAIL, May 13, 2013, https://www.wvgazettemail.com/news/small-town-faces-up-to-film-s-image-of-oxyana/article_ed5b0d1a-4072-5f70-b0e9-53434e92870f.html.

[580] Marlow Stern, *'Oxyana' Documentary, at Tribeca, Exposes the OxyContin Epidemic*, DAILY BEAST, Apr. 23, 2013, https://www.thedailybeast.com/oxyana-documentary-at-tribeca-exposes-the-oxycontin-epidemic?ref=scroll.

[581] AmerisourceBergen Corp., Customer Due Diligence Questionnaire Checklist – Westside Pharmacy, Jan. 11, 2016 (On file with Committee).

[582] *See* E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to AmerisourceBergen Corp. (July 23, 2018 3:13 pm) (On file with Committee).

[583] *See* E-Mail from Counsel to AmerisourceBergen Corp., to Staff, H. Comm. on Energy and Commerce (Aug. 17, 2018 4:46 pm) (On file with Committee).

**FINDING: AmerisourceBergen began doing business with Westside Pharmacy again in January 2016. Documents produced to the Committee give no indication to suggest that AmerisourceBergen considered the company's 2012 decision to place stricter limits on the pharmacy's ability to purchase controlled substances.**

Setting aside the prior engagement, the due diligence materials provided by Westside Pharmacy in December 2015 should have raised other red flags which, based on the documents provided to the Committee, were apparently not adequately investigated by AmerisourceBergen.

In the Retail Pharmacy Questionnaire completed by Westside Pharmacy, the pharmacy noted its ability to purchase controlled substances had been either terminated or restricted by a wholesale distributor in the past.[584] Based on the questionnaire, it is not clear whether Westside Pharmacy was referring to the prior restriction on controlled substance ordering imposed by AmerisourceBergen, or a different distributor that suspended or ceased controlled substance sales in the past. The Committee's investigation found that Westside Pharmacy submitted its Retail Pharmacy Questionnaire to AmerisourceBergen on the same day it was terminated by Miami-Luken after the company received an Order to Show Cause from the DEA, which included allegations regarding Miami-Luken's distribution to Westside Pharmacy.[585]

In the prospective customer questionnaire, the pharmacy also provided AmerisourceBergen with its top five prescribing physicians for either hydrocodone or oxycodone.[586] Three of the five names on the list should have raised concerns—Dr. Sanjay Mehta, Dr. Michael Kostenko, and Dr. David Morgan.

### *A. Dr. Sanjay Mehta*

Dr. Mehta practiced at the HOPE Clinic in Beaver, West Virginia. In March 2015, approximately nine months prior to Westside Pharmacy's application to AmerisourceBergen, federal and state law enforcement officials raided Dr. Mehta's office,[587] and the West Virginia

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[584] AmerisourceBergen Corp., Retail Pharmacy Questionnaire – Westside Pharmacy, Dec. 9, 2015 (On file with Committee).

[585] *See* E-Mail from Dir. Compliance and Security, Miami-Luken, Inc. to Diversion Investigator, U.S. Drug Enforcement Admin. and Diversion Investigator, U.S. Drug Enforcement Admin. (Dec. 11, 2015 3:36 pm) (On file with Committee). In this e-mail to the DEA, Miami-Luken told the DEA "[o]n 12/09/2015, Miami-Luken terminated the controlled substance business relationship with Westside Pharmacy in Oceana, WV[.]" *See also* U.S. Drug Enforcement Admin., *In re Miami-Luken*, Order to Show Cause, Nov. 23, 2015 (On file with Committee).

[586] AmerisourceBergen Corp., Retail Pharmacy Questionnaire – Westside Pharmacy, Dec. 9, 2015 (On file with Committee).

[587] Daniel Tyson, *Update: Hope Clinic raided by various agencies*, REGISTER-HERALD, Mar. 19, 2015, http://www.register-herald.com/news/update-hope-clinic-raided-by-various-agencies/article_22bb2e49-ea58-54bd-8c73-e3d58be58a5d.html.

Department of Health and Human Resources subsequently ordered him to close his practice.[588] According to a press report from May 2015, citing documents obtained from the West Virginia Department of Health and Human Resources:

> Patient records at the Beaver HOPE clinic didn't contain enough information to identify patients. The records didn't support patient diagnosis or justify treatment, [West Virginia Department of Health and Human Resources] investigators reported. HOPE staff didn't document patients' health histories, current medications, or whether or not they were dependent on controlled substances or being treated at another pain clinic.[589]

Press reports also indicate that prior to the forced closure of the Beaver HOPE clinic, the West Virginia Department of Health and Human Resources also ordered a related HOPE clinic in Charleston, West Virginia to close in February 2015 for similar infractions.[590]

A press report available at the time AmerisourceBergen onboarded Westside Pharmacy indicates that following the forced closure of the Beaver HOPE clinic, Dr. Mehta relocated to Wytheville, Virginia in June 2015 where he continued to practice at another HOPE clinic.[591] Wytheville, Virginia is located approximately a four-hour round-trip drive from Westside Pharmacy, and the DEA license verification AmerisourceBergen had on file in its due diligence documents for Westside Pharmacy also reflects a Wytheville, Virginia address for Dr. Mehta. The press report also indicates that the Wytheville HOPE clinic was raided by the DEA on the same day the Beaver location was raided, March 19, 2015, and noted "[f]inding a pharmacy to

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[588] Jessica Farrish, *State investigative report reveals numerous violations at HOPE pain clinic*, REGISTER-HERALD, May 24, 2015, http://www.register-herald.com/news/state-investigative-report-reveals-numerous-violations-at-hope-pain-clinic/article_bf69155e-bec2-5ce6-9a19-53a26ce88670.html. Dr. Mehta was indicted by a federal grand jury on charges related to improperly prescribing controlled substances. If convicted, Dr. Mehta faces a minimum 40-year sentence up to life imprisonment. *See* Press Release, Dep't of Justice, U.S. Attorney's Office, S.D. W.Va., U.S. Attorney announces 69-count indictment charging owners, managers and physicians associated with Hope Clinic (Feb. 20, 2018), https://www.justice.gov/usao-sdwv/pr/us-attorney-announces-69-count-indictment-charging-owners-managers-and-physicians.

[589] Jessica Farrish, *State investigative report reveals numerous violations at HOPE pain clinic*, REGISTER-HERALD, May 24, 2015, http://www.register-herald.com/news/state-investigative-report-reveals-numerous-violations-at-hope-pain-clinic/article_bf69155e-bec2-5ce6-9a19-53a26ce88670.html.

[590] *See* Eric Eyre, *W.Va. pain clinics scrutinized; 3 facilities shut down*, CHARLESTON GAZETTE-MAIL, Mar. 29, 2015, https://www.wvgazettemail.com/news/w-va-pain-clinics-scrutinized-facilities-shut-down/article_3a5ee5b4-6b2c-53a9-a7c7-38bfe21c3422.html; *see also* Jessica Farrish, *State investigative report reveals numerous violations at HOPE pain clinic*, REGISTER-HERALD, May 24, 2015, http://www.register-herald.com/news/state-investigative-report-reveals-numerous-violations-at-hope-pain-clinic/article_bf69155e-bec2-5ce6-9a19-53a26ce88670.html; Associated Press, *Report: Closed pain clinic's practices put patients at risk*, WASH. TIMES, May 25, 2015 https://www.washingtontimes.com/news/2015/may/25/report-closed-pain-clinics-practices-put-patients-/; Daniel Tyson, *Update: Hope Clinic raided by various agencies*, REGISTER-HERALD, Mar. 19, 2015, http://www.register-herald.com/news/update-hope-clinic-raided-by-various-agencies/article_22bb2e49-ea58-54bd-8c73-e3d58be58a5d.html.

[591] *See* Wayne Quesenberry, *Wytheville clinic's neighbors complain*, SWVA TODAY, July 3, 2015, https://www.swvatoday.com/news/wytheville/article_da711ca0-2063-11e5-a7a4-0fd9119c9e66.html.

fill their prescriptions is a problem for many of the clinic's patients. Most local pharmacies won't accept them."[592]

### B. *Dr. Michael Kostenko*

Dr. Kostenko practiced at and operated the Coal Country Clinic in Daniels, West Virginia. In July 2015, the West Virginia Department of Health and Human Resources ordered the Coal Country Clinic to close after a state inspection found "incomplete record keeping with little documentation of patient diagnosis or assessment."[593] The clinic was ordered to close a second time in August 2015 and assessed civil money penalties after state inspectors found the clinic continued to operate in contravention of the July 2015 order.[594] Following a November 2015 hearing, Dr. Kostenko was ordered to discontinue operating the Coal Country Clinic as a pain clinic and to provide complete patient records to the West Virginia Department of Health and Human Resources.[595] At the hearing, an Assistant Attorney General for West Virginia noted, among other things, that Board of Pharmacy record showed that Dr. Kostenko had prescribed "an exorbitant amount of controlled substances."[596] In January 2016, only days before AmerisourceBergen approved Westside Pharmacy's application, Dr. Kostenko was prominently featured in a *CBS News* report where it was noted that Dr. Kostenko had written more than 40,000 opioid prescriptions over a two-year period.[597]

All of this information on Dr. Mehta and Dr. Kostenko had been publicly reported and was accessible to AmerisourceBergen at the time it was conducting its due diligence on Westside Pharmacy in late 2015 and early 2016.[598]

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[592] Wayne Quesenberry, *Wytheville clinic's neighbors complain*, SWVA TODAY, July 3, 2015, https://www.swvatoday.com/news/wytheville/article_da711ca0-2063-11e5-a7a4-0fd9119c9e66.html.

[593] Press Release, W. Va. Dep't of Health and Human Res., DHHR Petitions Court to Close Coal Country Clinic (Hearing scheduled for November 23, 2015) (Nov. 19, 2015), https://dhhr.wv.gov/News/2015/Pages/DHHR-Petitions-Court-to-Close-Coal-Country-Clinic.aspx.

[594] *See* Press Release, W. Va. Dep't of Health and Human Res., DHHR Petitions Court to Close Coal Country Clinic (Hearing scheduled for November 23, 2015) (Nov. 19, 2015), https://dhhr.wv.gov/News/2015/Pages/DHHR-Petitions-Court-to-Close-Coal-Country-Clinic.aspx. *See also* Eric Eyre, *DHHR goes to court to shut down Raleigh pain clinic*, CHARLESTON GAZETTE-MAIL, Nov. 19, 2015, https://www.wvgazettemail.com/news/cops_and_courts/dhhr-goes-to-court-to-shut-down-raleigh-pain-clinic/article_36816010-f278-5304-b603-b201de85fd6a.html and Kyla Asbury, *WVDHHR wants Raleigh County pain clinic shut down,* WEST VIRGINIA RECORD, Nov. 20, 2015, https://wvrecord.com/stories/510649252-wvdhhr-wants-raleigh-county-pain-clinic-shut-down.

[595] Sarah Plummer, *Coal Country Clinic to remain open as non-pain clinic, must prove compliance*, REGISTER-HERALD, Nov. 24, 2015, http://www.register-herald.com/news/coal-country-clinic-to-remain-open-as-non-pain-clinic/article_1153b547-4bcf-55a9-b8a5-ec8dbef08b66.html.

[596] *Id.*

[597] Jim Axelrod and Ashely Velie, *West Virginia allows painkiller addicts to sue prescribing doctors*, CBS NEWS, Jan. 6, 2016, https://www.cbsnews.com/news/west-virginia-allows-painkiller-addicts-to-sue-doctors-who-got-them-hooked/.

[598] Subsequently, Dr. Kostenko was arrested on federal charges related to improperly prescribing controlled substances and was eventually sentenced to 20 years in federal prison and ordered to pay a $50,000 fine after entering a guilty plea. *See* Press Release, Dep't of Justice, U.S. Attorney's Office, S.D. W.Va., Beckley area physician sentenced to 20 years in federal prison for oxycodone crime (Aug. 23, 2017), https://www.justice.gov/usao-sdwv/pr/beckley-area-physician-sentenced-20-years-federal-prison-oxycodone-crime.

The Committee asked AmerisourceBergen whether the company consulted or considered press reports related to Dr. Mehta and Dr. Kostenko when it was considering Westside Pharmacy's application.[599] In response, AmerisourceBergen informed the Committee that "[n]ews searches for prescribing physicians are not a standard part of ABDC's new customer review and there is no record of their having been performed in this instance."[600] Similarly, the due diligence documents that were produced to the Committee give no indication that AmerisourceBergen questioned the pharmacy about its relationship with either doctor.

**FINDING: Prior to onboarding Westside Pharmacy as a customer in January 2016, AmerisourceBergen does not appear to have consulted public news reports that would have alerted the company to red flags related to some of the pharmacy's top prescribing physicians. According to AmerisourceBergen, "[n]ews searches for prescribing physicians are not a standard part of ABDC's new customer review[.]"**

As part of its due diligence, AmerisourceBergen did verify the DEA and state licenses for the pharmacy's top-prescribing physicians, including Dr. Mehta and Dr. Kostenko. AmerisourceBergen also told the Committee that, notwithstanding that it did not conduct news searches on the top-prescribing physicians, it did conduct a search for any board actions that were taken against them.[601] With respect to Dr. Kostenko, the due diligence file contained a 2005 complaint issued by the West Virginia Board of Osteopathy which alleged that Dr. Kostenko allowed staff to perform unauthorized and medically unnecessary tasks.[602]

### C. *Dr. David Morgan*

Dr. David Morgan was listed as Westside Pharmacy's top prescriber of hydrocodone or oxycodone on the Retail Pharmacy Questionnaire.[603] As mentioned previously, Dr. Morgan's medical practice was located an approximate four-hour round-trip drive from Westside Pharmacy. Setting this aside, not only did the due diligence materials produced to the Committee contain derogatory information related to Dr. David Morgan, but external investigators hired by AmerisourceBergen independently flagged Dr. Morgan as cause for concern earlier in 2015.[604]

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[599] *See* E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to AmerisourceBergen Corp. (July 23, 2018 3:13 pm) (On file with Committee).

[600] E-Mail from Counsel to AmerisourceBergen Corp., to Staff, H. Comm. on Energy and Commerce (Aug. 17, 2018 4:46 pm) (On file with Committee).

[601] *Id.*

[602] *In re: Michael Kostenko, D.O.*, Complaint and Notice of Hearing (W. Va. Bd. of Osteopathy) (On file with Committee).

[603] *See* AmerisourceBergen Corp., Retail Pharmacy Questionnaire – Westside Pharmacy, Dec. 9, 2015 (On file with Committee).

[604] The Virginia Board of Medicine sanctioned Dr. Morgan for releasing a patient with known substance abuse issues but failing to provide a referral to substance abuse treatment while simultaneously providing the patient with five prescriptions for opioids, some of which were post-dated. The patient had recently been hospitalized for overdosing on Lortab, which is a pharmaceutical that contains hydrocodone and acetaminophen. *In re: David Lee*

The due diligence documents produced to the Committee illustrate that AmerisourceBergen attempted to verify Dr. Morgan's DEA and state registrations but discovered that a registration number for Dr. Morgan indicated that his license was expired. An AmerisourceBergen business development manager e-mailed Westside pharmacy's owner, requesting an updated DEA license number for Dr. Morgan. Rather than provide an updated DEA license number, the pharmacy owner instead gave a long explanation of the town's relationship with Dr. Morgan in an e-mail to an AmerisourceBergen employee, stating, in part, "[y]ou tell compliance that I will agree to not fill any of his scripts reguardless [sic] if he practiced here in my town or not."[605] The e-mail from the pharmacy owner is reproduced below:

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*Morgan, D.O.*, Consent Order, 1-2 (Va. Board of Medicine, Oct. 14, 2008) *available at* http://www.dhp.virginia.gov/Notices/Medicine/0102201292/0102201292Order10142008.pdf. In December 2016, Dr. Morgan had his license to practice medicine suspended indefinitely by the Virginia Board of Medicine upon the board's determination that his practice of medicine presented "substantial danger to the public health and safety." *See In re: David Lee Morgan, D.O.*, Notice (Va. Board of Medicine, Dec. 15, 2016) *available at* http://www.dhp.virginia.gov/Notices/Medicine/0102201292/0102201292Notice12152016.pdf. Dr. Morgan is currently under federal investigation for his controlled substance prescribing practices. According to an affidavit submitted by federal investigators, twenty of Dr. Morgan's patients died of drug overdoses between January 2011 and August 2016. Jeff Surgeon, *Former Giles County doctor, stripped of license, faces federal criminal probe*, ROANOKE TIMES, Apr. 18, 2017, http://www.roanoke.com/news/local/former-giles-county-doctor-stripped-of-license-faces-federal-criminal/article_ccfcd2ad-684d-52c2-87c0-078f7dff8445.html.

[605] E-Mail from Owner, Westside Pharmacy to Business Development Manager, AmerisourceBergen Corp. (Dec. 23, 2015 3:22 pm) (On file with Committee). In contrast to the representation made by Westside Pharmacy's owner in the December 23, 2015 e-mail that the pharmacy was "not disciplined by Miami Luken [sic] for any wrong doing [sic] or finding[,]" Miami-Luken represented to the Committee that its decision to terminate Westside Pharmacy as a customer on December 9, 2015 was based on multiple factors, including, "the pharmacy's failure to identify top opioid prescribers who were subject to, or a party to, disciplinary action" and "deceitful practices on the part of the owner[.]" The latter concern related to Westside Pharmacy's continuing to fill prescriptions written by Drs. Morgan and Mehta, months after representing to Miami-Luken that it would no longer fill prescriptions that were written by either doctor. *See* Letter from Counsel to Miami-Luken, Inc., to Hon. Greg Walden, Chairman H. Comm. on Energy and Commerce, Mar. 28, 2018 (On file with Committee). Miami-Luken terminated its relationship with Westside Pharmacy after it received an Order to Show Cause from the DEA, which included allegations regarding Miami-Luken's distribution to Westside Pharmacy. *See* U.S. Drug Enforcement Admin., *In re Miami-Luken*, Order to Show Cause, Nov. 23, 2015 (On file with Committee); *see also* Transcript of Interview of Dr. Joseph R. Mastandrea, Chairman of the Board, Miami-Luken Inc., by Staff, H. Comm. on Energy and Commerce, Dec. 13, 2017, 91 (On file with Committee).

**From:** [redacted]
**Date:** December 23, 2015 at 3:22:36 PM EST
**To:** [redacted]
**Subject: Re: FW: CSRA Review Requested for WESTSIDE PHARMACY (21355)**

listen...even though dr morgan was in this town for 14 years and then relocated across the border 1 hr 45 min away people still go there. He has treated theses patients for 20 plus years. We are 1 hour 1/2 from closest pain treatment clinic. So my decisions to treat his patients were for the customers. It seems this Dr David Morgan which I do feel I know him on a very personal professional level if creating problems. You tell compliance that I will agree to not fill any of his scripts reguardless if he practiced here in my town or not. I have to take care of my children that need add meds etc. Miami Luken assured me that my account was only moderate dispensing 17% control and 7 percent c2. I don't understand. I have always been compliant. but I will prove to your company that I am trustworthy. You make the guidelands and I will follow 100 percent... I need this account NOW before I have to file bankruptcy. Dougs Drugs are opening in a few weeks.. I can't turn business away. This is detrimental to my business..I was not disciplined by Miami Luken for any wrong doing or finding. That can be verified. I will abide by any policies you have with controls.

Thanks [redacted]

The due diligence documents provided to the Committee do not indicate whether AmerisourceBergen attempted to address the e-mail that was sent by the pharmacy's owner or if the company conducted any additional due diligence on the pharmacy's relationship with Dr. Morgan.

AmerisourceBergen should have been particularly attuned to Dr. Morgan's prescribing, however, given that external investigators hired by AmerisourceBergen to review another West Virginia pharmacy highlighted Dr. Morgan's prescribing practices in a February 2015 report.[606] The investigators determined that Dr. Morgan was one of the top prescribing physicians at this pharmacy and noted, "Dr. David Morgan, DO wrote for 1,852 oxycodone prescriptions and 212 Oxycontin prescriptions in 2012. Dr. Morgan currently has a case pending with the Virginia Board of Medicine."[607] AmerisourceBergen told the Committee it placed the pharmacy at issue in the report on the company's 'Do Not Ship list' following the February 2015 review.[608]

AmerisourceBergen, however, does not appear to have applied this information to other pharmacies where it knew Dr. Morgan was a top prescriber. At a minimum, the materials AmerisourceBergen provided to the Committee documenting its late 2015 and early 2016 due diligence of Westside Pharmacy contain no reference to the company's February 2015 findings relating to Dr. Morgan.

AmerisourceBergen's due diligence file for its 2015-2016 examination of Westside Pharmacy did include documentation from the Virginia Board of Medicine (Board) related to previous disciplinary actions that had been taken against Dr. Morgan. Included in the due

[606] *See* The Pharma Compliance Group, Observations and Recommendations Report, Feb. 15, 2015 (On file with Committee).
[607] *Id.*
[608] *See* Letter from Counsel to AmerisourceBergen Corp., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., May 7, 2018 (On file with Committee). AmerisourceBergen stated that it removed this pharmacy from the Do Not Ship list in May 2016 after conducting additional due diligence.

diligence files were consent orders that were entered in 2008 and 2014, including the Board's certification of Dr. Morgan's compliance thereof.[609]

The 2014 consent order also should have served as a significant cause for concern for AmerisourceBergen during its evaluation of Westside Pharmacy, considering Dr. Morgan was identified as the pharmacy's top prescriber of hydrocodone or oxycodone on the Retail Pharmacy Questionnaire. For example, the consent order—included in AmerisourceBergen's due diligence file for the pharmacy—included multiple instances in which Dr. Morgan prescribed medications, including oxycodone, without having seen the patient.[610] Relevant excerpts from the consent order are reproduced below:

| | |
|---|---|
| 5/22/03,12/16/03, 3/15/05, 1/26/07, 11/25/08, 12/18/10, 2/11/11, 3/21/12 | On each of these dates, Dr. Morgan wrote renewal prescriptions, including oxycodone, OxyContin 40, OxyContin 20, MS Contin, Percocet, Oxy IR 5, Demerol, Duragesic, morphine sulfate, Adderall, and/or Xanax without having seen the patient. |
| 5/24/05, 12/11/06, 2/4/08, 3/31/08, 5/27/08, 5/25/10 | On each of these dates, Dr. Morgan wrote renewal prescriptions, including OxyContin, morphine sulfate, Roxicodone, oxycodone, and/or Xanax without having seen the patient. |
| 4/2/07, 5/31/07, 6/9/07, 7/27/07 8/28/07, 10/25/07, 12/20/07, 2/18/08, 3/17/08, 8/4/09, 9/29/10 | On each of these dates, Dr. Morgan wrote renewal prescriptions for OxyContin 40, OxyContin 20, OxyIR5, Endocet, and/or Xanax without having seen the patient. |
| 2/5/07, 7/27/07, 5/27/08, 12/22/09, 6/17/10, 9/9/10, 4/20/11, 6/15/11 | On each of these dates, Dr. Morgan wrote renewal prescriptions for Lorcet, Oxy IR5, oxycodone, Percocet, and/or Xanax without having seen the patient. |
| 4/19/05 | Dr. Morgan noted that the patient was taking excessive amounts of Percocet, but took no action to address this and in fact increased the daily dose at the patient's next visit. |
| 5/18/06, 7/24/06, 7/12/07, 3/31/08, 5/27/08, 6/15/11, 9/29/11, 11/1/11, 2/23/12, 3/21/12, | On each of these dates, Dr. Morgan wrote renewal prescriptions for Percocet, Oxy IR5, Roxicodone, morphine sulfate, Dilaudid, and/or Xanax without having seen the patient. |

The Board also found that Dr. Morgan failed to take any corrective action after learning that some of his patients used multiple pharmacies to have their prescriptions filled. In one

[609] The due diligence file from AmerisourceBergen's 2011 review of Westside Pharmacy did not include the 2008 consent order involving Dr. Morgan, even though Dr. Morgan was one of six physicians listed on a document entitled "Westside Pharmacy Pain Doctors."

[610] *In re: David Lee Morgan, D.O.*, Order, 6 -7 (Va. Bd. of Med., Mar. 24, 2014) *available at* http://www.dhp.virginia.gov/Notices/Medicine/0102201292/0102201292Order03242014.pdf.

instance, the Board noted "Dr. Morgan failed to take corrective action when presented with information that Patient H had utilized at least eleven (11) different pharmacies in at least three (3) states to obtain his narcotic and benzodiazepine prescriptions authorized by Dr. Morgan between 2008 and 2011."[611]

The Committee asked AmerisourceBergen whether it took Dr. Morgan's history of disciplinary action into account when it was performing due diligence on Westside Pharmacy in late 2015 and early 2016, and to provide any due diligence material that would document any such consideration.[612] In response, AmerisourceBergen stated "[r]egarding Dr. Morgan, the file contains licensure information, a follow-up exchange with Westside Pharmacy regarding Dr. Morgan's licensure, and multiple disciplinary records."[613] AmerisourceBergen went on to state, "ABDC reviewed those records for Dr. David Morgan and considered his disciplinary record."[614]

In a one-page Customer Due Diligence Questionnaire Checklist included in the due diligence file and described by the company as "[a] record of the review conducted on the due diligence file[,]"[615] AmerisourceBergen indicated that it performed due diligence on the pharmacy's high prescribing physicians and verified the distance between the pharmacy and prescribers.[616] The Customer Due Diligence Questionnaire Checklist stated:

**Prescribers**

- ☐ Start-up entity
- ☒ Due Diligence has been completed on listed high prescribing physicians (verify DEA, verify state license and board actions)
- ☒ Verified Suspect Prescriber List
- ☒ Verified distance between prescribers and pharmacy

Despite the indication on this document, however, the due diligence documents produced to the Committee give no indication that AmerisourceBergen actually considered the distances between Westside Pharmacy and its prescribing physicians. As mentioned earlier, Drs. Morgan and Mehta were located approximate four-hour round-trip drives from Westside Pharmacy. The DEA has identified a pharmacy filling prescriptions written by physicians located significant distances from the pharmacy as being a red flag of diversion.[617]

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[611] *In re: David Lee Morgan, D.O.*, Order, 3 (Va. Bd. of Med., Mar. 24, 2014) *available at available at* http://www.dhp.virginia.gov/Notices/Medicine/0102201292/0102201292Order03242014.pdf.

[612] E-Mail from Staff, H. Comm. on Energy and Commerce, to Counsel to AmerisourceBergen Corp. (July 23, 2018 3:13 pm) (On file with Committee).

[613] E-Mail from Counsel to AmerisourceBergen Corp., to Staff, H. Comm. on Energy and Commerce (Aug. 17, 2018 4:46 pm) (On file with Committee).

[614] *Id.*

[615] *Id.*

[616] AmerisourceBergen Corp., Customer Due Diligence Questionnaire Checklist – Westside Pharmacy, Jan. 11, 2016 (On file with Committee).

[617] *See* 77 Fed. Reg. 62,321, Oct. 12, 2012 (In the order, the DEA Administrator adopted the ruling of the DEA ALJ that found expert testimony credible that prescribing doctors located more than 200 miles from pharmacies were red flags that were not resolvable and controlled substances should not have been dispensed by the pharmacies.).

**FINDING: In December 2015, when Westside Pharmacy submitted a prospective customer application to AmerisourceBergen, two of the pharmacy's top prescribers of opioids were located four-hour round-trip drives from the pharmacy.**

During two separate prospective customer reviews, AmerisourceBergen was provided with information regarding some of Westside Pharmacy's prescribing physicians that should have raised serious red flags for the company. Had the company examined these red flags and sought an explanation from the pharmacy in 2011, it may have reached a different conclusion regarding the pharmacy's initial new customer application. When AmerisourceBergen received Westside Pharmacy's new customer application in December 2015, it should have examined its prior history with the pharmacy. Had the company done so, it would have seen that the pharmacy had a history of supplying opioids to distant physicians with disciplinary and criminal histories related to improper prescribing, and that the company itself took previous action to limit the pharmacy's ability to order controlled substances. While such a retrospective review should be standard due diligence practice, the factors presented to AmerisourceBergen in 2015 and 2016 alone provided the company with a more than sufficient basis for it to have reached a different conclusion regarding Westside Pharmacy's application.

### e. *Case Study on H.D. Smith: Analyzing a Prospective Customer's Existing Due Diligence File*

In the course of this investigation, the Committee identified many instances where a distributor received a new customer application from a pharmacy that a distributor had a preexisting relationship with, either as a former customer or as a past applicant. In such situations, consulting the existing due diligence files for the pharmacy may provide a distributor with important background information, aiding a distributor's ability to assess the pharmacy's current new customer application. This is especially so in situations where—unlike other case studies in this section where the due diligence files from previous encounters were incomplete—the due diligence files maintained by a distributor indicate that it had previously identified red flags related to the pharmacy's dispensing practices or had documented action taken to restrict a pharmacy's ability to purchase controlled substances.

Family Discount Pharmacy, located in Mount-Gay Shamrock, West Virginia, had a population of 1,779 in 2010.[618] H.D. Smith was one of multiple distributors that supplied Family Discount Pharmacy, which received more than 16.59 million dosages of hydrocodone and oxycodone from all distributors between 2006 and 2016.[619] Between December 2007 and February 2011, H.D. Smith supplied Family Discount Pharmacy with more than 1.5 million doses of hydrocodone and oxycodone.[620] Between April 2015 and December 2016, H.D. Smith supplied Family Discount Pharmacy with an additional 628,020 doses of hydrocodone and oxycodone.[621]

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[618] American FactFinder, *Mount Gay-Shamrock CDP, West Virginia* (https://factfinder.census.gov).
[619] U.S. Drug Enforcement Admin., ARCOS Data (On file with Committee).
[620] *Id.*
[621] *Id.*